Implementation of guidelines on family involvement for persons with psychotic disorders

A cluster randomised trial with mixed methods evaluation

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Table of contents

Summary in English

Background: Psychotic disorders usually have a substantial impact on the life and well-being of both patients and their relatives. Scientific evidence suggests that family interventions, such as 'family psychoeducation' (FPE), lead to significantly improved outcomes for persons with psychotic disorders, their relatives, and the public health and welfare services. Despite the documented effects, and their translation into clinical practice guidelines, the implementation of family interventions in mental health care is generally poor and irregular, resulting from barriers at the policy, organisational, and clinical levels. In Norway, the Directorate of Health has issued general recommendations on family involvement in the health and care services and clinical practice guidelines that recommend family interventions in the treatment of psychotic disorders. Frameworks and methods for implementation and intervention research may provide useful strategies and tools for the implementation of such guidelines in mental health care. Previous studies on the implementation of FPE in mental health services have either used a non-randomised study design or been unable to show a significant increase in fidelity to the model.

Aim: The aim of the 'Implementation of Family Involvement for persons with Psychotic disorders' (IFIP) study was to implement the national guidelines on family involvement for persons with psychotic disorders in Norwegian community mental health centres (CMHCs). The purpose of this thesis was to give an overview of the IFIP study (Article 1), to describe and evaluate the implementation process with quantitative methods (Articles 2 and 3), and to explore clinicians' perceptions of family involvement through qualitative methods (Article 4).

Methods: The IFIP study employed a cluster randomised design where 14 clusters, consisting of one or more CMHC units, were randomised to either the experimental or control arm with an allocation ratio of 1:1. Experimental clusters received an 'implementation support programme' (ISP) for 18 months to implement the national guidelines, whereas the control clusters did not. The project group developed the complex IFIP intervention, which consisted of both clinical- and implementation interventions, to operationalise the guidelines. The clinical interventions were FPE and basic family involvement and support (BFIS). The implementation interventions included the appointment of a family coordinator and an implementation team, clinical training and supervision, a toolkit, and fidelity measurements with onsite feedback and supervision. In addition, the ISP included a focus on leadership commitment, systematic stakeholder engagement, and a whole-ward approach, which meant offering agency-wide education and recommending multidisciplinary delivery of family involvement.

The processes and effectiveness of clinical and implementation interventions were evaluated through a hybrid effectiveness-implementation and mixed methods design. This thesis includes large parts of the implementation- and clinical process evaluations, as well as the implementation effectiveness evaluation. Fidelity assessments were carried out at baseline, 12, 18, and 24 months in the experimental arm, and at baseline and 24 months in the control arm. During the fidelity assessments, we measured adherence to the national guidelines with the newly developed basic family involvement and support (BFIS) scale and the FPE fidelity scale, but also individualisation and quality improvement related to FPE with the general organisational index (GOI). We further recorded the FPE 'penetration rate' at each site; the

percentage of eligible patients that had received the intervention. Difference in change on the FPE fidelity scale, between experimental and control arm, was the primary outcome. The baseline data was analysed with descriptive statistics, a non-parametric test, and calculation of interrater reliability for the scales. The data from all the measurements was analysed with an independent samples t-test, linear mixed models, and a tobit regression model.

We performed a qualitative study, based on 8 focus groups with implementation teams and 5 focus groups with ordinary clinicians, to explore their experiences with family involvement in the treatment of persons with psychotic disorders, regarding perceived benefits and disadvantages for patients, relatives, and themselves, including possible mediating factors and processes. The data was analysed with reflexive thematic analysis.

Results: At baseline, the participating CMHCs lacked organisational structures, standardisation, and procedures for family involvement, and few patients with psychotic disorders and their relatives had received BFIS or FPE. The mean scores on all three scales were moderate to low. The new BFIS scale showed promising preliminary psychometric properties. At 24 months, the mean scores on all the scales indicated adequate to high levels of implementation in the experimental arm, whereas the scores were generally moderate to low in the control arm. The increase in scores on all scales was significantly larger in experimental clusters than control clusters, and the FPE penetration rate also rose significantly in the experimental arm, from 6.76 to 12.84 %. The results showed a significant effect of the ISP on the level of adherence to the national guidelines in the experimental arm, when compared to no implementation support in the control arm.

The explorative qualitative study showed that clinicians mainly reported positive experiences with family involvement in the treatment of persons with psychotic disorders. Four main themes were identified as perceived benefits: 1. Family psychoeducation – a concrete framework. 2. Reducing conflict and stress. 3. A triadic understanding, and 4. Being on the same team. Themes 2-4 were linked to three important clinician-facilitated sub-themes; a space for relatives' experiences, emotions and needs; a space to discuss sensitive topics and, an open line of communication. Perceived disadvantages or challenges were less frequent, but we identified the following three main themes: 1. Family psychoeducation – occasional poor model fit or difficulties following the framework. 2. Getting more involved than usual, and 3. Relatives as a potentially negative influence – important nonetheless.

Conclusion: The implementation results of the IFIP study were very good compared to previous studies on the implementation of family involvement in mental health services. Findings from the qualitative study both complemented and corroborated the results of previous qualitative studies of family involvement. Clinicians' perceptions of the clinical interventions' characteristics may have influenced the implementation outcomes, such as fidelity and penetration. Regardless of the limitations of the study design and methods, the interventions, measures, instruments, and findings of the IFIP study should be highly relevant to policy makers, health service units, administrators, and clinicians who wish to implement family involvement in mental health services. Future research should focus on identifying cost-efficient and feasible measures to scale up family involvement, together with mixed methods process evaluations of high quality.

Sammendrag

Bakgrunn: Psykoselidelser har som regel en betydelig innvirkning på livene og trivselen til både pasienter og deres pårørende. Vitenskapelig evidens tyder på at familieintervensjoner, slik som 'psykoedukativt familiesamarbeid' (PEF), fører til signifikant bedrede utfall for personer med psykoselidelser, deres pårørende og de offentlige helse- og velferdstjenestene. Til tross for de dokumenterte effektene, og deres innlemmelse i kliniske retningslinjer, er implementeringen av pårørendesamarbeid i psykiske helsetjenester generelt lav og varierende, et resultat av hemmere på politisk, organisatorisk og klinisk nivå. I Norge har Helsedirektoratet gitt generelle anbefalinger om pårørendesamarbeid i helse- og omsorgstjenestene og kliniske retningslinjer som anbefaler familieintervensjoner i behandlingen av psykoselidelser. Rammeverk og metoder for implementerings- og intervensjonsforskning kan gi nyttige strategier og verktøy for implementering av slike retningslinjer i psykisk helsevern. Tidligere implementeringsstudier, av PEF i psykiske helsetjenester, har enten anvendt et ikke-randomisert studiedesign eller ikke kunnet påvise en signifikant økning i troskap til modellen.

Formål: Formålet med 'Bedre PårørendeSamarbeid' (BPS)-studien var å implementere nasjonale retningslinjer for pårørendesamarbeid ved psykoselidelser i norske Distriktspsykiatriske Sentre (DPS). Hensikten med denne avhandlingen var å gi et overblikk over BPS-studien (Artikkel 1), å beskrive og evaluere implementeringsprosessen med kvantitative metoder (Artikkel 2 og 3), samt å utforske behandlernes syn på pårørendesamarbeid med kvalitative metoder (Artikkel 4).

Metoder: BPS-studien anvendte et klyngerandomisert design hvor 14 klynger, bestående av en eller flere DPS-enheter, ble randomisert til enten intervensjons- eller kontrollarmen med en allokasjonsratio på 1:1. Intervensjonsarmen mottok et 'implementeringsstøtteprogram' (ISP) i 18 måneder for å implementere de nasjonale retningslinjene, mens kontrollarmen ikke fikk det. Prosjektgruppen utviklet den komplekse BPS-intervensjonen, som bestod av både kliniske- og implementeringsintervensjoner, for å operasjonalisere retningslinjene. De kliniske intervensjonene var PEF og 'grunnleggende pårørendesamarbeid' (GPS). Implementeringsintervensjonene omfattet blant annet utnevnelsen av en pårørendekoordinator og et implementeringsteam, klinisk opplæring og veiledning, en 'verktøy'-pakke, og troskapsmålinger med tilbakemeldinger og veiledning gitt lokalt. I tillegg så inkluderte ISP'et et fokus på ledelsesforankring, systematisk involvering av sentrale aktører, og en tilnærming som omfattet hele enheten gjennom tilbud om opplæring til alle ansatte og en anbefaling om at de alle skulle kunne tilby pårørendesamarbeid.

Prosessevaluering og effektevaluering av både kliniske- og implementeringsintervensjoner foregikk gjennom et hybrid studiedesign, med fokus på både implementering og klinisk effekt, og gjennom kombinert bruk av kvalitative og kvantitative metoder. Denne avhandlingen omfatter både deler av prosessevalueringen og evalueringen av implementeringsstøttens effekt. Troskapsmålinger ble gjennomført før implementeringen startet og deretter ved 12, 18 og 24 måneder i intervensjonsarmen, samt før oppstart og ved 24 måneder i kontrollarmen. Under troskapsmålingene målte vi hvorvidt enhetene fulgte de nasjonale retningslinjene, med den nyutviklede BPS-skalaen og PEF-troskapsskalaen, samtidig som vi målte individualisering og

kvalitetsforbedring relatert til PEF med den generelle organisasjonsindeksen (GOI). Videre målte vi 'penetransen' av PEF ved hver enhet; andelen av de aktuelle pasientene som hadde mottatt intervensjonen. Primærutfallet var forskjellen i endring, mellom intervensjons- og kontrollarm, på PEF-troskapsskalaen. Dataene fra før implementeringen ble analysert med deskriptiv statistikk, en ikke-parametrisk test, og beregning av reliabilitet mellom målerne. Dataene fra alle målingene ble analysert med en t-test for uavhengige utvalg, lineære blandede regresjonsmodeller og en tobit regresjonsmodell.

Vi gjennomførte en kvalitativ studie, basert på 8 fokusgrupper med implementeringsteam og 5 fokusgrupper med ordinære behandlere, for å utforske deres erfaringer med pårørendesamarbeid i behandlingen av psykoselidelser, med hensyn til opplevde fordeler og ulemper for pasienter, pårørende og dem selv, inkludert mulige medierende faktorer og prosesser. Disse dataene ble analysert med refleksiv tematisk analyse.

Resultater: Før implementeringen manglet deltagerenhetene organisatoriske strukturer, standardisering og prosedyrer for pårørendesamarbeid, og få pasienter med psykoselidelser og deres pårørende hadde mottatt GPS eller PEF. Gjennomsnittlig skåre på samtlige tre skalaer var moderat til lav. Den nye BPS-skalaen viste lovende foreløpige psykometriske egenskaper. Etter 24 måneder tilsa gjennomsnittsskårene i intervensjonsarmen at de hadde adekvate til høye implementeringsnivåer, mens skårene i kontrollarmen generelt var moderate til lave. Økningen i skåre på samtlige skalaer var signifikant større hos intervensjonsenheter enn kontrollenheter og penetransen av PEF økte også signifikant i intervensjonsarmen, fra 6.76 til 12.94 %. Resultatene viste en signifikant effekt av ISP'et på intervensjonsenhetenes implementering av de nasjonale retningslinjene, sammenliknet med ingen implementeringsstøtte i kontrollarmen.

Den utforskende kvalitative studien viste at behandlerne i hovedsak beskrev positive erfaringer med pårørendesamarbeid i behandlingen av personer med psykoselidelser. Fire hovedtemaer ble identifisert som opplevde fordeler: 1. Psykoedukativt familiesamarbeid – et konkret rammeverk. 2. Å redusere konflikt og stress. 3. En triadisk forståelse, og 4. Å være på samme lag. Tema 2-4 var forbundet med tre viktige undertemaer som behandlerne la til rette for; et rom for pårørendes erfaringer, følelser og behov; et rom for å diskutere vanskelige temaer og, en åpen kommunikasjonslinje. Opplevde ulemper eller utfordringer ble beskrevet sjeldnere, men vi identifiserte følgende tre hovedtemaer: 1. Psykoedukativt familiesamarbeid – tidvis uegnet eller vansker med å følge strukturen. 2. Å bli mer involvert enn tidligere, og 3. Pårørende som en potensielt negativ innflytelse – viktige likevel.

Konklusjon: Implementeringsresultatene i BPS-studien var veldig gode sammenliknet med tidligere studier på implementering av pårørendesamarbeid i psykiske helsetjenester. De kvalitative funnene samsvarte med tidligere liknende studier, men tilførte også ny innsikt. Behandlernes oppfatning av de kliniske intervensjonene kan ha påvirket implementeringsutfall, slik som troskap og penetrans. Til tross for begrensninger ved studiens design og metoder så bør intervensjonene, tiltakene, instrumentene og funnene fra BPS-studien være høyst relevante for beslutningstagere, helsetjenesteenheter, ledere og behandlere som ønsker å implementere pårørendesamarbeid i psykiske helsetjenester. Fremtidig forskning bør fokusere på å finne kostnadseffektive og gjennomførbare tiltak for å oppskalere pårørendesamarbeid, sammen med prosessevalueringer av høy kvalitet som kombinerer kvantitativ og kvalitativ metode.

List of articles

This thesis is based on the following articles, which will be referred to by their numerals.

Article 1

Hestmark L, Romøren M, Heiervang KS, Weimand B, Ruud T, Norvoll R, Hansson KM, Norheim I, Aas E, Landeweer EGM, Pedersen R. *Implementation of guidelines on family involvement for persons with psychotic disorders in community mental health centres (IFIP): protocol for a cluster randomised controlled trial.* BMC Health Services Research. 2020;20(1):934. doi: 10.1186/s12913-020-05792-4

Article 2

Hestmark L, Heiervang KS, Pedersen R, Hansson KM, Ruud T, Romøren M. *Family involvement practices for persons with psychotic disorders in community mental health centres - a cross-sectional fidelity-based study.* BMC Psychiatry. 2021;21(1):285. doi: 10.1186/s12888-021-03300-4

Article 3

Hestmark L, Romøren M, Heiervang KS, Hansson KM, Ruud T, Šaltytė Benth J, Norheim I, Weimand B, Pedersen R. *Implementation of Guidelines on Family Involvement for Persons with Psychotic Disorders (IFIP): A Cluster Randomised Controlled Trial.* Administration and Policy in Mental Health and Mental Health Services Research. 2023;50(3):520-33. doi: 10.1007/s10488-023-01255-0

Article 4

Hestmark L, Romøren M, Hansson KM, Heiervang KS, Pedersen R. *Clinicians' perceptions of family involvement in the treatment of persons with psychotic disorders: a nested qualitative study.* Frontiers in Psychiatry. 2023;14:1175557. doi: 10.3389/fpsyt.2023.1175557

List of figures and tables

Abbreviations

ACT	Assertive Community Treatment
BFIS	Basic Family Involvement and Support
BFIS-P	Basic Family Involvement and Support scale – penetration subscale
BFIS-S	Basic Family Involvement and Support scale – fidelity subscale
BPB	Bedre PsykoseBehandling (Norwegian research project)
BPS	Bedre PårørendeSamarbeid (Norwegian study acronym)
CFI	Camberwell Family Interview
CFIR	Consolidated Framework for Implementation Research
CI	Confidence interval
CMHC	Community Mental Health Centre
DPS	Distriktspsykiatrisk senter (Norwegian acronym for CMHC)
EBP	Evidence-based practice
EE	Expressed emotion
EPOC	Effective Practice and Organisation of Care (Cochrane group)
ERIC	Expert Recommendations for Implementing Change
FACT	Flexible Assertive Community Treatment
FFT	Family-Focused Therapy
FPE	Family Psychoeducation
FQ	Family Questionnaire
GDPR	General Data Protection Regulation
GOI	General organisational index
GP	General practitioner
GPS	Grunnleggende pårørendesamarbeid (Norwegian acronym for BFIS)
ICC	Intraclass correlation coefficient
ICD-10	The International Classification of Diseases 10th version
IDDT	Integrated Dual Disorders Treatment
IFIP	Implementation of Family Involvement for Persons with Psychotic Disorders (Study acronym)

IMR Illness Management and Recovery

IRR Inter-rater reliability

ISP Implementation Support Programme

LMM Linear mixed model

MRC Medical Research Council

NEBP National Evidence-Based Practices (US research project)

NICE National Institute for Health and Care Excellence

PAR Participatory action research

PDSA Plan-Do-Study-Act cycle

PEF Psykoedukativt familiesamarbeid (Norwegian acronym for FPE)

PVO Personvernombud (Norwegian acronym for data protection officer)

R&D Research and development

REC Regional Committee for Medical and Health Research Ethics

SD Standard deviation

SDM Shared decision-making

SE Supported Employment

SRQR Standards for Reporting Qualitative Research

StaRI Standards for Reporting Implementation Studies

TIPS Treatment and Intervention in Psychosis (Scandinavian research project)

TIPS South-East: The Early Intervention in Psychosis Advisory Unit for Southeast Norway.

TSD Tjenester for Sensitive Data (Norwegian acronym (Services for Sensitive Data))

1. Introduction

The implementation of family involvement for persons with psychotic disorders in mental health services is generally poor and irregular (1-4), regardless of the scientific evidence that demonstrates major beneficial effects for patients, relatives, and the public health and welfare services (5-8). This is arguably one of the most severe evidence-to-practice gaps in mental health care today.

There are barriers to implementation at the policy, organisational, and clinical levels (9). Some of these are general obstacles to the adoption of new practices within the health services, whereas others may constitute specific barriers to implementing family involvement in mental health care. To bridge this evidence-to-practice gap, the Norwegian Directorate of health has issued general guidelines on family involvement in the health and care services (10), and clinical practice guidelines that recommend the use of family interventions as part of the treatment for persons with psychotic disorders (11). However, the creation and distribution of guidelines as an individual measure seems insufficient to alter clinical practice (12).

This thesis constitutes a central part of the evaluation of a cluster randomised trial to address this issue in Norwegian community mental health centres (CMHCs), from 2019 to 2020. The aim of the study was to improve the cooperation between patient, relative, and clinician, as well as the psychosocial health of patients and adult relatives, by implementing the national guidelines on family involvement for persons with psychotic disorders. Thus, it was called the 'Implementation of Family Involvement for persons with Psychotic disorders' (IFIP) study, or 'Bedre PårørendeSamarbeid' (BPS) in Norwegian.

At the beginning of the IFIP study, we did not have in-depth knowledge of the level of adherence to the national guidelines in Norwegian CMHCs, although we suspected that it was generally low. There was also no instrument available to measure basic family involvement and support comprehensively in mental health care. To our knowledge, no cluster randomised trial had achieved a significant increase in fidelity to the Family Psychoeducation (FPE) model, one of the best documented family interventions for persons with psychotic disorders. Finally, qualitative studies of clinicians' experiences with FPE and similar models had rarely explored the potential benefits and mediating processes of family involvement, as part of the treatment for persons with psychotic disorders.

This thesis will provide an overview of the IFIP study through our published study protocol (Article 1) (13). It will also show how we created an instrument to measure basic family involvement practices, and how we measured the baseline level of adherence to the national guidelines in participating clinical sites (Article 2) (14). Furthermore, it will describe how we created a multilevel complex intervention and an implementation support programme (ISP), which substantially and significantly increased the level of adherence to the national guidelines in the experimental arm (Article 3) (15). Finally, it will provide a qualitative exploration of clinicians' perceptions of family involvement in the treatment of persons with psychotic disorders, regarding benefits and potential challenges (Article 4) (16).

2. Background

2.1. Family involvement for persons with psychotic disorders in mental health care

In this chapter, I will describe central concepts and definitions; the historical and theoretical foundations of family involvement in mental health care; family involvement models and frameworks and the evidence supporting these; guidelines and recommendations, and the status of, and barriers to, implementation. The chapter also includes two sections describing the Norwegian context, mental health services, guidelines, and recommendations. When describing the status of knowledge, I have included articles published before, during, and after the IFIP study so that these sections are nearly up to date. However, I have left out all the articles published as part of our project in order not to interfere with the narrative structure of the thesis.

2.1.1. Basic concepts and definitions

The focus of the present thesis is on persons with psychotic disorders, i.e. diagnoses F20-29 in 'The International Classification of Diseases' (ICD-10) (17), and their relatives. Since the former receive treatment in specialised health services, they are referred to in this thesis as 'patients', being the appropriate clinical and legal term in Norway. In Norwegian we employ the term 'pårørende' to describe those in the immediate social context of the patient, whether it be a parent, child, spouse, partner, friend, or other significant person. The Norwegian term 'nærmeste pårørende' is equivalent with the English term 'next of kin' and denotes the closest family member or significant other that has a special status in the health legislation. Throughout this thesis, the terms 'relative', 'family', and 'next of kin' are used to describe adult persons that offer considerable and unpaid support to a person with a psychotic disorder. The term 'family involvement' means the systematic inclusion of relatives in the assessment, treatment, and follow-up of the patient, but also efforts to address the needs of the relatives themselves. While the scope of this thesis is limited to persons with psychotic disorders, the family involvement practices described will often be relevant for persons with other forms of severe mental illness, such as bipolar and major depressive disorders.

2.1.2. Psychotic disorders and relatives' roles, experiences, and needs

Although the course and severity of the illnesses vary considerably, psychotic disorders are characterised by so-called 'positive symptoms' such as hallucinations and delusions, and 'negative symptoms' such as emotional apathy and social withdrawal, and these symptoms are often accompanied by reduced functioning, cognitive impairment, and altered behaviour (18). Thus, psychotic disorders usually have a profound effect on the life and well-being of both patients and their relatives.

Relatives may have a number of different roles, such as providing informal care and emotional, practical, or financial support to the patient (1). They may also act as representatives when a patient lacks the capacity to consent to treatment or hospital admission and are frequently the

first to notice a clinical deterioration, thus often left with the responsibility to alert the health services (19). Relatives usually have detailed knowledge about the patient and may contribute to both the assessment and follow-up by providing clinicians with valuable information (20).

It is important to recognise the potential impact of schizophrenia and other severe mental illnesses on the patients' families. The scientific literature has usually divided the negative effects into subjective and objective caregiver burden, where objective burden refers to concrete aspects such as financial hardship and family disruption. Subjective burden, on the other hand, refers to the psychological impact of the patient's illness on their relatives (19, 21, 22). For family caregivers of persons with schizophrenia, the subjective burden may include traumatic experiences related to symptoms or crisis situations, feelings of guilt or shame, and feelings of loss concerning expectations for the patient's life that went unfulfilled, or for their own personal life and health. They might also experience a sense of uncertainty and unpredictability regarding the course and manifestations of the illness. Objective burden may include a lack of personal, financial, or social resources, as well as insufficient understanding and skills to handle the illness, but also stigma, family disruption, and conflicts between family members, with the patient, or with health professionals (21). This may lead to reduced participation in social activities and a loss of social support because of increased tasks and responsibilities and a reluctance to discuss the illness with other people (19). Relatives also have a generally higher risk of becoming ill themselves (23), and in some instances they may become victims or suffer as a result of the patient's actions (20). However, the term 'caregiver burden' has been criticised for not including positive experiences or the possibility for reciprocal support (24). Relatives also report positive aspects of being a caregiver, such as increased affection, compassion, affirmation, and family solidarity, in addition to personal growth and increased self-confidence (21).

Research has shown that relatives may require emotional and practical support, with tailored information and guidance to understand the illness, treatment, and the health services, and to develop coping strategies and problem-solving skills (19).

2.1.3. Historical and theoretical foundations of family involvement in mental health care

Notions such as the 'schizophrenogenic mother', who was described as cold and rejecting while simultaneously being overprotective and promoting dependence, had a detrimental influence on health professionals' attitudes and practice in the previous century. When health professionals assumed that negative traits of caregivers or family dynamics contributed significantly to the development of schizophrenia and other severe mental illnesses, their interactions with the patients' relatives often became characterised by rejection, hostility, contempt, or covert blame, resulting in harm to both relatives and patients (25).

The realisation that family pathology or dysfunction was not the principal cause of schizophrenia came gradually, when conventional family therapy to address these supposed issues proved ineffective and sometimes even harmful (26). At the end of the 20th century, the 'diathesis-stress' theory gained prominence in explaining the pathogenesis and remission and relapse patterns of severe mental illnesses, parallel with the rise of the 'biopsychosocial' model

(27) of understanding human health and disease in general. According to the diathesis-stress theory, psychotic episodes or relapses might be triggered in a person who has a genetic predisposition for schizophrenia, by environmental factors that are perceived as stressful (28). The vulnerability to stress and the specific stressors involved are highly individual, but some environmental factors are associated with a higher relapse rate in epidemiological studies (29).

Among these, we find the concept of 'expressed emotion' (EE), which is central to understanding the development of family involvement as an evidence-based practice (EBP). EE is an empirically derived construct to describe the family environment and includes the negative dimensions critical comments, hostility, and emotional over-involvement, which can be measured with psychometric instruments such as 'the Family Questionnaire' (FQ) (30) and 'the Camberwell Family Interview' (CFI) (31). The critical difference between the theory of EE and the previous assumptions of family dysfunction is that elevated EE is regarded as a reaction pattern to stress, which usually reflects the family's attempt to cope with the situation rather than an inherent pathology of the family. Unfortunately, a high level of EE can lead to clinical deterioration for the patient, which then further increases the stress on the family and generates a vicious circle (26). Recent meta-analyses and reviews confirm that a high level of EE increases the risk of relapse significantly for persons with schizophrenia (29, 32). However, regarding elevated EE as a reaction to stress also means that these reactions can be recognised and altered through cognitive behavioural techniques (25). Finally, it is important to emphasise that many families of persons with schizophrenia do not show high levels of EE and that the concept also includes the positive dimensions of warmth and positive remarks, where warmth may protect against relapse (32) and both dimensions might predict life satisfaction among patients (33).

The reconceptualisation of the family, from pathogenic to partners in care, should also be seen in the context of important societal and health service changes at the end of the 20th century. From the late 1970s onwards, psychiatric hospitals were gradually replaced by community mental health services. The deinstitutionalisation was made possible by the discovery of effective psychotropic medication, but was also a response to legitimate criticism of psychiatric confinement and the asylums (34). Public financial incentives did also play a role in the closure of psychiatric hospitals and critics have later claimed that the reduction in hospital beds went too far (35, 36), and that adequate community services and resources were not in place (37). For many relatives, the deinstitutionalisation process entailed a dramatic increase in their caring responsibilities since their family member with severe mental illness came to live at home or in their local community (8).

The need for effective community-based services and the ascendancy of the evidence-based paradigm led to the development of several treatment and rehabilitation interventions, including FPE (38). To be considered an EBP, a psychosocial intervention like FPE must be shown to be consistently effective through randomised controlled studies (39). Thus, the evidence-based paradigm not only helped dispel the previous notions of 'pathological families' by showing that conventional family therapy was ineffective, but also contributed to the establishment of FPE as an essential part of psychosis treatment.

During the same period, reforms aimed to limit coercive measures and paternalism by promoting 'shared decision-making' (SDM) and recovery-oriented services. According to Charles et al. (40), the key characteristics of SDM are that at least two participants - physician and patient - are involved; that both parties share information; that both parties take steps to build a consensus about the preferred treatment, and that an agreement is reached on the treatment to implement. Involving relatives in the SDM process as part of the information exchange would seem like a sensible extension of the model, but is far from standard practice (41). The personal recovery paradigm emphasises the values, preferences, and goals of the person with mental illness (42) and involves 'The establishment of a fulfilling, meaningful life and a positive sense of identity founded on hopefulness and self-determination' (43). This approach contrasted highly with the predominant symptom and medication-focused paradigm and placed significant emphasis on the relationships and social environment of the patient (42), where relatives may have an important role in facilitating recovery (44, 45).

2.1.4. Family involvement models and frameworks

To address the needs of both patients with severe mental illness and their relatives, various models for family involvement in mental health care have been developed during the last four decades. While these models are based on diverse views of the causes, nature, and treatment of mental illness, they also share a number of characteristics such as a focus on communication, SDM, and family support (46). The theoretical underpinnings of these family involvement models can be roughly categorised as the diathesis-stress theory (described above), systems theories, and postmodern theories, where the models may be grounded in one or several of these. Systems theories generally assume that there is a problem within the family system that causes or triggers illness, whereas postmodern theories are critical of the biomedical narratives and understanding of mental illness and emphasise that these problems must be understood and solved in a social context (46). Family involvement models of varying durations, formats, and therapeutic philosophies are referred to broadly as 'family interventions' in the scientific literature, a term which also includes peer-led educational and support programmes (19, 47). Web-based educational and support measures have also been developed (48, 49), but these are outside the scope of the present thesis.

The most widely used and well-documented group of structured family interventions, which can be offered in a single- or multifamily format, are those labeled 'family psychoeducation' (FPE) (38). FPE models are firmly grounded in the diathesis-stress and biopsychosocial paradigms, but are also influenced by systems theories (46). The models' aim is to reduce EE and to provide the patient and relatives with emotional support, information about the illness and treatment, recognition of warning signals, communication and coping skills, and structured problem-solving exercises. These interventions "…are essentially cognitive-behavioral therapy with consistent inclusion of family members as collaborators" (26). In the US, central contributions to the present models have been the FPE model developed by Anderson, Hogarty, & Reiss (50), 'behavioural family therapy' developed by Falloon, Boyd, & McGill (51) with later contributions from Mueser and Glynn (52), 'multifamily group therapy' developed by McFarlane (53), and 'Family-Focused Therapy' (FFT) developed by Miklowitz and Goldstein

(54). In the UK, the work of Leff et al. (55) and Tarrier et al. (56) also contributed significantly to the establishment of FPE as an EBP.

According to the World Schizophrenia Fellowship (1998) rendered by McFarlane (2016) (26), the central characteristics of these models are that FPE:

- *Assumes that most involved family members of individuals with mental illnesses need information, assistance, and support to best assist their ill family member and cope with the often severe challenges posed to the family system.*
- *Assumes that the way in which relatives behave toward and with the person with mental illness can have important effects, both positive and sometimes negative, on that person's well-being, clinical outcomes, and functional recovery.*
- *Combines informational, cognitive, behavioral, problem solving, communication, and consultative therapeutic elements.*
- *Is initiated and led by mental health professionals.*
- *Is offered as part of a clinical treatment plan for a specific patient/consumer.*
- *Focuses primarily on benefiting consumer/patient outcomes, but improvements for family members (e.g., reducing confusion, exasperation, and emotional distress) are also essential to achieve those outcomes.*
- *Includes:*
  - *content about illness, medication, and treatment management;*
  - *services coordination;*
  - *attention to all parties' expectations, emotional reactions, and distress;*
  - *assistance with improving family communication;*
  - *structured problem solving and instruction;*
  - *implementing individualized coping and rehabilitative strategies;*
  - *expanding social support networks; and*
  - *explicit crisis planning with professional involvement.*
- *Are generally diagnosis specific, although cross-diagnosis models have been developed and are often the de facto practice.*

Since FPE interventions usually last for 9 months or longer (1), briefer and less resource-demanding models consisting of 1-10 sessions have also been developed. These include ‘brief family education’, where the focus is on psychoeducation, coping strategies, and community resources, and ‘brief family consultation’, which usually aims to resolve specific issues or address specific goals identified by the patient or the relatives (19, 57). The Family Forum conference in 2008 (57) introduced the principle of sufficiency to describe the transitions between these simpler family interventions and FPE. They describe family services as composed of various interventions of increasing complexity, where a flowchart indicates the appropriate level of intervention based on the patient’s and the family’s needs (57).

A similar, but more comprehensive model is found in Mottaghipour and Bickerton’s ‘The Pyramid of Family Care - a framework for family involvement in adult mental health services’

(58). In this article, they describe family involvement practices as being on a continuum from basic to advanced, illustrated by a stratified pyramid where the two lowest layers constitute 'a minimum level of care'. Layer 1 includes the successful connection with the relatives, assessment of their needs, listening to their experiences, documentation, basic information provision, and establishing a system of safety, e.g. a crisis/coping plan. Layer 2 contains general education about the illness, treatment, mental health services, families and patients' rights, as well as available support measures. Their framework embodies three important concepts. Firstly, by employing the term 'a minimum level' they assert that there is such a thing as a basic or essential level of family involvement that should be offered to all patients and their relatives, and that every adult mental health worker should have this competence. Secondly, like the Family Forum, the pyramid shows how this 'minimum level' is a necessary foundation for advanced family interventions, such as FPE (layer 3). Finally, the framework emphasises the dynamic, flexible, and continuous nature of family involvement, by including a reassessment of needs on levels II-V, showing that one should move up and down the pyramid depending on the family's situation (58).

2.1.5. The evidence supporting family interventions for persons with psychotic disorders

Since the 1980s, scientific studies documenting beneficial effects of family interventions for persons with psychotic disorders, their relatives, and the public health and welfare services have been steadily accumulating. During the last two decades, this has enabled researchers to conduct evidence synthesis through systematic reviews and meta-analyses. There is also growing evidence to support family interventions for other forms of severe mental illness, including bipolar disorders (59) and major depressive disorder (60), but the focus of this overview will be limited to psychotic disorders.

In 2010, Pharoah et al. (5) updated the Cochrane review investigating the effects of family psychosocial interventions in community settings for people with schizophrenia or schizophrenia-like conditions, compared with standard care. It showed that family interventions may lower the frequency of relapse, as well as the number and length of hospital admissions, and promote adherence with pharmacological treatment, but the effect on patients and relatives tendency to leave care was uncertain. The review also suggested that interventions could reduce social impairments, family burden, and the level of EE within the family. There were no detectable effects on employment, independent living, or imprisonment. Some included studies reported favourable effects on symptoms/mental state, but because of variations in study design and the scales used, the overall effect was regarded as equivocal. Economic analyses favoured family interventions, with a reduction in direct or indirect costs compared to standard care (5).

Later systematic reviews and meta-analyses have confirmed the findings that family interventions appear to lower relapse rates and hospital admissions, while also improving functioning (6, 7, 61, 62) and increasing adherence with medication (63, 64) among persons with psychotic disorders. There is also evidence to suggest that family interventions reduce overall/total symptoms (6, 7, 62, 65) and contribute to increased quality of life for patients (61, 66). For persons with recently diagnosed or first-episode psychosis, there is evidence of reduced

relapse rates (67), hospital admissions, and days spent in hospital (68, 69). A recent systematic review and meta-analysis also indicated reduced symptoms and increased functioning, but the included data were heterogeneous (69).

If we consider outcomes for relatives and families of persons with psychotic disorders, studies have shown increased carer satisfaction (61), reduced family burden, increased family function, altered family attitudes (70), increased knowledge and coping skills (71), as well as reduced global morbidities, negative caregiver experiences, perceived burden, and the level of EE (72). For relatives of persons with recently onset psychosis, studies report a reduction in carer burden and the level of EE (67), improved caregiving experience, and improved utilisation of formal support and family functioning (73). For relatives of persons with severe mental illness (including psychotic disorders), psychoeducation may improve the experience of caregiving as well as caregivers' psychological distress (8).

While the effects of family interventions in general for persons with psychotic disorders and their relatives seem well documented, there has also been a significant interest in comparing the effects of various models, formats, and durations. The above-mentioned reviews that made such comparisons found either no significant differences (5, 70), or that mutual support may improve family function more than psychoeducation in the long term (73), whereas a review from 2002 found that the drop-out from multifamily groups may be higher than from single-family groups (74). A Cochrane review from 2014 (75) compared brief (three sessions or less) family-oriented psychosocial interventions for schizophrenia with treatment as usual. The authors found a significant increase in the acceptance and understanding by family members, whereas the effects on relapse and hospitalisation were equivocal (75).

However, two recent articles published in the Lancet Psychiatry sum up the existing knowledge within this field. Bighelli et al. (6) published a systematic review and network meta-analysis of psychosocial and psychological interventions for relapse prevention and other relevant outcomes in schizophrenia in 2021. They made a broad distinction between family interventions and FPE, where the latter has a primary focus on information provision. Both family interventions and FPE appeared to lower relapse rates 12 months after the intervention, compared to treatment as usual. They both seemed to reduce overall symptoms, but only FPE had an effect on positive symptoms and none of them seemed to affect negative symptoms. Family interventions were superior to most of the other psychosocial and psychological interventions investigated, in terms of improved functioning (6).

In 2022, Rodolico et al. (7) published a systematic review and network meta-analysis, which may be regarded as an update to a meta-analysis from 2001 (76). The article investigated the effect of family interventions specifically for relapse prevention and other relevant outcomes among persons with schizophrenia. It differentiated between systemic-oriented family interventions, psychoeducational approaches to the family with the patient, psychoeducational interventions to the family without the patient, integrated interventions where patient and family received separate interventions, and control conditions such as brief family interventions and treatment as usual. Within these categories, there were several sub-groups. The authors found that nearly all the interventions reduced relapse at 12 months compared to treatment as usual, except brief FPE (two sessions or less) and a crisis-oriented FPE model with patient and

relative(s) that did not include the educational elements that are now standard in most psychoeducational approaches. FPE (patient and relative(s) together) in its simplest form, without behavioural elements and skills training, was associated with a lower probability of relapse than most other interventions. The secondary outcomes were highly heterogeneous, but pairwise meta-analyses that included at least two studies with non-heterogeneous results showed that overall symptoms were reduced by an intervention where patient and relatives received psychoeducation separately and by community-based care. Positive symptoms were reduced by FPE combined with family behavioural or skills training (broad) and by community-based care. The latter also reduced negative symptoms and increased functioning (7).

2.1.6. Mediating factors, processes, and qualitative explorations

By comparing the effects of various family interventions, systematic reviews and meta-analyses may contribute to the identification of the critical elements or minimal duration required to achieve certain outcomes. A highly interesting finding of Rodolico et al. (7) was that psychoeducation with patient and relative, without behavioural elements or skills training, might be even more effective in preventing relapse than the more complex models. However, it is possible that the addition of behavioural elements or skills training contribute to some of the other documented outcomes among patients and relatives, such as reduced carer burden or increased quality of life. Although there is a consensus regarding the theoretical foundations and standard elements of the FPE models, we have less knowledge about their mediating factors and critical elements, including the processes involved (57).

The value of qualitative methods to investigate the processes and dynamics of EBPs has been increasingly recognised (77). A review by Grácio et al. from 2016 (78) aimed to identify the active ingredients of family interventions for psychosis by conducting a systematic literature review including both quantitative and qualitative research. They concluded that therapeutic alliance, support, education, coping skills training, and the reframing of relatives' views about patients' behaviour and symptoms appeared to be the key ingredients of successful family interventions. Similar to the findings of the psychotherapy outcome literature, they suggested that common therapeutic factors, i.e. therapeutic alliance, support, and the opportunity for sharing, might contribute significantly to the effectiveness of family interventions. Finally, the review indicated that education increases knowledge about the illness and that the subsequent reframing of relatives' views is an important mediator in lowering EE, which then reduces the risk of relapse (78).

Later qualitative studies on stakeholders' perceptions of family interventions seem to corroborate these findings. Nilsen et al. (79, 80) describes how patients with first-episode psychosis and their relatives participating in mainly multifamily FPE groups valued the initial separate meetings with the clinician to build trust and alliance. Openness and trust also characterised the group sessions, where participants felt they could share their experiences freely and listen to the experiences of other families. The increased understanding of symptoms and reframing of how relatives perceived the patients' behaviour, with consequent adjustment of expectations, was considered important, and reduced conflict and stress at home was

attributed to improved communication. Studies on the experiences of patients with psychotic disorders and their relatives with similar interventions report many of the same findings (81), but also describe increased mutual understanding, as well as increased family cohesion among some participants (82, 83). However, qualitative studies on clinicians' perceptions of FPE have tended to focus on barriers and challenges, rather than perceived benefits and mediating processes (84, 85). Qualitative investigations have also reported benefits of basic family involvement practices as an integrated part of inpatient wards (86, 87), early intervention services (88, 89), and assertive outreach teams (90). Yet, to our knowledge, no qualitative studies have explored the benefits, interactions, and processes when combining basic family involvement practices with more advanced family interventions for persons with psychotic disorders.

2.1.7. Guidelines, implementation status, and barriers

As the previous sections clearly show, there are substantial arguments in favour of implementing family involvement in the treatment of persons with psychotic disorders. The scientific evidence has been synthesised, summarised, and graded to create clinical practice guidelines that recommend family interventions as a first-line treatment during all stages of the illness (11, 18, 61, 91-93). Clinical practice guidelines have usually been based on evidence synthesis from efficacy studies, where skilled and motivated clinicians provide an intervention to carefully selected study participants. However, an increasing number of clinical trials have focused on testing effectiveness, where pragmatic selections of target populations and clinical staff is meant to resemble intervention delivery and effect under real-life conditions. A systematic review of the studies included in the 'National Institute for Health and Care Excellence' (NICE) guidelines on psychological and psychosocial interventions for psychotic disorders showed that 33.6 % of these had a pragmatic approach and that 49.7 % could be categorised as somewhere between pragmatic (effectiveness) and explanatory (efficacy) (94).

If we consider how relatives provide unpaid care and support that save public health services significant costs (8), and their need for information, guidance, and support to cope with their role and situation (19), there are also compelling moral arguments in favour of increased family involvement and support. From a socio-economic perspective, employing one of the most effective treatments available, while making full but judicious use of informal care resources, should be a priority. With usual onset during youth or early adulthood, psychotic disorders often require complex and tailored healthcare services over time and lead to significant productivity loss and increased use of social and welfare services (23, 95). A Danish study showed that the sum of direct and indirect costs were 4-10 times higher than for chronic neurological disorders, and that spouses of patients with schizophrenia had nearly 10 times higher use of health and welfare resources than the general population (23). An English study found that carers of people with psychosis had significantly poorer mental health than a general population sample, and that partners and single carers were especially at risk (96). Thus, family involvement and support in the mental health services is not only crucial to improve the assessment, treatment, follow-up, and health of patients, but should also be regarded as a preventive public health measure, to preserve good health, quality of life, and coping abilities among the next of kin.

Such ethical and socio-economic considerations, combined with the efforts of carer advocacy groups and active policies to strengthen informal care, have in some countries led to the development of general recommendations on family involvement and support in the health and care services (10, 97).

However, studies indicate that the implementation of family interventions in mental health services is generally poor and irregular (1-4, 98, 99). Investigations have also found that family caregivers usually experience an insufficient level of involvement, cooperation, and support from mental health services (100-106). Demonstrated effectiveness does not guarantee public health impact through increased adoption of EBPs (107), and developing and distributing guidelines without further measures seems insufficient to close the evidence-to-practice gap (12). Significant barriers to implementation exist at both the clinical and organisational levels (9). While some of these constitute barriers to implementing EBPs in general, other barriers may be more specific to the implementation of family involvement in mental health care.

There are several EBPs that have been under-implemented in mental health services, reflecting the challenges of translating evidence into regular clinical practice (12, 108). General barriers to the implementation of EBPs, which also affect the implementation of family involvement, include a lack of resources, structure, procedures, training, supervision, skills and confidence among clinicians, as well as insufficient leadership commitment and prioritisation, staff shortages and turnover, short-term perspectives, and conflicting professional views (1, 3, 4, 9, 109-112).

In addition, there are obstacles that may be particular to the implementation of family involvement in mental health care. One example is the influential biomedical paradigm, where the focus has been on symptoms, medication, and individual therapy rather than on the patients' social context, family, and network (4, 9, 109, 110). There may also be residual notions of the historical paradigms in which the family was considered responsible for the patient's illness (1, 9). The predominant organisational culture and clinicians' attitudes often include the view that family involvement is peripheral to the main tasks of a mental health service unit, something optional for those particularly interested, and this may lead to a lack of integration with the remaining services and treatment modalities (4, 9). At the policy level, the situation is made worse by the lack of financial incentives and reimbursements for conducting family involvement in mental health care (1).

At the clinical level, the various stakeholders report divergent perspectives and interests concerning barriers to family involvement, sometimes revealing a lack of trust between clinician, patient, and relative(s) (110). Patients are concerned about burdening their relatives; do not expect family involvement to be beneficial or perceive it as stressful; fear a breach of privacy or losing control of sensitive information; are afraid of losing their role within the family, and are reluctant to involve family members who misunderstand their illness (9, 110, 111, 113). From the relatives' perspective, barriers to family involvement include: the patient being dishonest or too unwell; concerns about privacy and confidentiality; low expectations of effect; lack of recognition by or patronising/negative attitudes of mental health workers, and an excessive focus on confidentiality among health professionals (9, 110, 113). Both patients and relatives describe stigma as an important hindering factor (1, 110). Clinicians report a fear of

breaching confidentiality and a lack of consent from the patient as major barriers. Additional barriers include: the patient being too ill; a lack of 'suitable' or 'competent' families; families who prefer not to be involved; family conflicts; not wanting to burden the family; low expectations of effect, and a lack of competence and experience to conduct family involvement (9, 110, 111). Sometimes, cultural background or language barriers are also perceived as hindering family involvement (9, 110).

Thus, any systematic effort to implement family involvement in mental health services will need to address both general and specific barriers, at both clinical and organisational levels.

2.1.8. Norwegian general policies, legislation, and recommendations on family involvement

In Norway, strengthening informal care across the entire health and care sector has been a priority in recent years, with the Norwegian government launching a national strategy and action plan in 2020 concerning relatives in the health and care services (114). The strategy listed three main objectives: 1) acknowledging relatives as a resource; 2) ensuring good and comprehensive care for all relatives so that they can live good lives for their own part and combine the carer role with education and work, and 3) ensuring that no child should have to take on carer responsibilities for family members or other persons (114). This national policy has been complemented by local initiatives, such as Oslo municipality's 'Oslo Standard for Family Collaboration', which aimed to ensure that collaboration with relatives was a systematic and integrated part of all health and care services within the municipality (115).

The Norwegian health legislation provides all relatives with certain rights towards the health and care services, including the right to general information about the health services, legal rights and roles, and available support measures. If they are familiar with the patient's diagnosis, relatives have a right to general information about the etiology, symptoms, diagnostic assessment, treatment, and prognosis. Health personnel may always listen to relatives and discuss information that is already known to them without breaching confidentiality. The nearest relative or another significant person, usually appointed by the patient, is given a formal status in the health legislation as the 'next of kin'. If a patient lacks the capacity to consent to treatment, the next of kin should be contacted, informed, and given the opportunity to share with health professionals what they think the patient's normal preferences would be. The next of kin also has the right to file a formal complaint when disagreeing on the establishment or termination of coercive treatment measures or involuntary hospitalisations. Both when the patient lacks capacity and when coercive treatment is used, the next of kin has a right to information, guidance, and to be involved in the delivery of treatment and follow-up (116-118). Health and care services are further obligated to provide relatives with appropriate training and guidance, particularly when the carer role entails a substantial amount of daily tasks and responsibilities (119, 120). Since 2010, specialised health services have been mandated by law to appoint local personnel who are responsible for following up children who are close relatives of patients with serious illnesses (119).

By combining these legal regulations with research evidence, ethical considerations, and discussions between key stakeholders and experts, the Norwegian Directorate of Health issued

national recommendations on family involvement and support in the health and care services in 2017 (10). A central aim of these recommendations was that relatives should become involved in the health and care services, to the benefit of the patient and themselves. The document describes how the health and care services have a duty to ensure family involvement and support, to provide health personnel with the relevant competence, and to ensure cooperation on family involvement between health service levels, as well as with the public welfare and voluntary sector. It contains sections on how to identify relatives, clarify their role, and document the relevant information in the patient's medical records. The recommendations further describe how to involve relatives in the assessment, treatment, and follow-up of the patient, and how to support them during various phases of the patient's illness trajectory. There is also a chapter dedicated to information and support for children who are close relatives of a patient, and a final chapter on how to handle ethical dilemmas connected to family involvement (10).

At the beginning of the IFIP study, there were no evaluations of the implementation of these national recommendations available, but the Directorate of Health commissioned a general evaluation from the company Oslo economics in 2021 (121). Their report documented varying knowledge and use of the recommendations, where those working with patients were less likely to be familiar with them than leaders and administrators (121).

2.1.9. Norwegian mental health services, guidelines, and clinical care pathways

The Norwegian public health and care services have two organisational levels with separate financing. Specialised health services are run by 19 separate health trusts, administered by four regional health authorities on behalf of the state, whereas the municipalities run municipal health and care services. Care and treatment of persons with severe mental illness, such as psychotic disorders, is offered by both specialised services and municipalities (122).

Specialised mental health services include hospital-based acute and rehabilitation wards, but also 66 CMHCs, which serve specific catchment areas and are located closer to where their clients live. They consist of various outpatient clinics, assertive outreach teams, and inpatient facilities, while collaborating closely with both hospital-based specialised services and community-based municipal services (122). 'Flexible Assertive Community Treatment' (FACT) teams are part of the CMHCs, but frequently have employees from both the specialised and municipal services (123).

Depending on their clinical status, comorbidity, and place of residence, persons with psychotic disorders may receive outpatient treatment from CMHC units such as specialised psychosis policlinics, joint psychosis and bipolar policlinics, early intervention services, rehabilitation teams, dual disorder treatment units, general psychiatric outpatient clinics, or assertive outreach teams such as the FACT teams. Many of them also receive municipal health and care services, including housing, home-based services, practical and social support, activity centres, and follow-up by mobile teams and their general practitioner (GP). Some receive treatment from psychiatrists or psychologists who run a private practice, and these are normally funded by the health trusts (122, 124).

In 2013, the Norwegian Directorate of Health published national clinical practice guidelines on the assessment, treatment, and follow-up of persons with psychotic disorders, based on a synthesis of the available evidence (11). The guidelines recommend that procedures for collaboration with relatives should focus on knowledge exchange, guidance, and support, and that the patient's treatment should contain an individually adapted combination of evidence-based active elements, such as medication, FPE, and cognitive behavioural therapy. In the early phase of a psychotic disorder, the guidelines recommend offering patients and relatives single-family psychoeducation, whereas multifamily groups are recommended for patients with chronic or long-term disorders and their families. Basic family involvement and support is recommended at every stage of the illness (11).

To ensure that patients receive well-organised, safe, comprehensive, and predictable mental health services without undue delay of assessment, treatment, and follow-up, the Norwegian government instituted national clinical pathways for mental health and addiction in January 2019 (125). The pathways set standards and deadlines for documentation, diagnostic evaluations, treatments, and follow-up measures, by operationalising the national clinical practice guidelines. They contain recommendations on family involvement and support similar to the guidelines, but the wording is generally vaguer and frequently includes the reservation 'where applicable' (125). An evaluation of the first two years of implementation of the clinical pathways was published by the research institute SINTEF in 2021, which may be viewed as an indirect and limited assessment of the implementation of the national guidelines in mental health services (126). The report shows that relatives found it difficult to obtain adequate information, that they had to take the initiative themselves to get information from professionals and to be adequately involved, and that they had very little influence on the patient's treatment. The relatives generally felt a need to be more involved during the assessment phase and to be able to provide information to assist the diagnostic process. Many felt that there was limited follow-up of themselves from the services and wished to have more frequent contact. Very few relatives had received information about relevant support measures or peer organisations (126).

Two additional reports should be mentioned when it comes to the level of family involvement in Norwegian mental health services. The first report contains an investigation of mental health services from 2021 by the Office of the Auditor General of Norway, where they conclude that many municipalities and specialised mental health services do not ensure adequate user and family involvement (127). The second report was published by the Norwegian Healthcare Investigation Board in 2023 and is based on their investigations of a serious incident in 2021, where a person with severe mental illness murdered five people. They concluded that inadequate family involvement was a contributing factor to the perpetrator not receiving sufficient mental health care prior to the incident (128).

2.2. Frameworks and methods for implementation and intervention research

In this chapter, I will introduce frameworks and methods for implementation and intervention research, including the Medical Research Council (MRC)'s framework for developing and evaluating complex interventions (129, 130); selected implementation science frameworks and methodology; implementation and evaluation strategies from mental health services research; mixed methods evaluation, and stakeholder engagement. Most of these frameworks and methods were consulted or used actively during the development, implementation, and evaluation phases of the IFIP study, while all of them will be employed in the methods and discussion sections of this thesis. The present chapter will provide an introduction and overview, while the methods section will detail how specific frameworks and methods were used and integrated during the IFIP study, and finally the discussion section will address some of the central theoretical and methodological questions associated with them.

2.2.1. The complex interventions framework

The UK MRC published a framework for developing and evaluating complex interventions in 2000, which was updated in 2008 by the MRC (130), and again in 2021 by the MRC and the National Institute for Health Research (129). Although not limited to the field of health, the framework has been most influential within public health and health services research. According to the latest framework: 'An intervention might be considered complex because of properties of the intervention itself, such as the number of components involved; the range of behaviours targeted; expertise and skills required by those delivering and receiving the intervention; the number of groups, settings, or levels targeted; or the permitted level of flexibility of the intervention or its components' (129). While these inherent characteristics of complex interventions were described in the 2008 version (130), the new framework places a larger emphasis on how interactions between the intervention and its context might lead to complexity, and the importance of understanding how and under what circumstances the intervention generates change (129). Since nearly all health interventions can be described as more or less complex, critics have questioned the need for a separate framework for complex interventions in health services research. However, it might be more useful to define investigations as complex interventions research based on the research questions asked and the methodology used, rather than on traits of the intervention itself (131). The updated guidance describes how complex interventions research may focus on efficacy or effectiveness. Studies may employ a theory-based approach, asking how the intervention works and under what circumstances, as well as a systems approach, investigating how the intervention and a given system adapt to one another (129).

The complex interventions framework provides detailed guidance on each of the central phases of intervention research, including the development, adaption, or identification of the intervention, feasibility and piloting, evaluation, and implementation (129, 130). These phases are not necessarily sequential, and the updated framework emphasises how one may start at any point in the process and repeat phases if necessary, depending on the uncertainties that need to be addressed. In the updated framework, all the phases share some core elements that are

important to consider at each step: '…considering context, developing and refining programme theory, engaging stakeholders, identifying key uncertainties, refining the intervention, and economic considerations' (129). The book 'Complex interventions in health', edited by Richards and Rahm Hallberg in 2015, elaborates on the various phases and provides additional insight into the complex interventions framework (132). Further guidance on the development phase was published in 2019 (133) and a separate framework for process evaluations of complex interventions was published in 2015 (134, 135). The guidance on process evaluation is a particular strength of the complex interventions framework, illustrating how both quantitative and qualitative methods can be used to investigate the context, implementation, and mechanisms of impact of an intervention. This is essential to understand whether the intervention was implemented properly, how it works in practice, and to explore contextual factors affecting its implementation and intended outcomes (134, 135).

2.2.2. Implementation science

The complex interventions framework might be said to follow the traditional research pipeline from efficacy to effectiveness to implementation, and focuses primarily on how to test efficacy or effectiveness while conducting a thorough process evaluation. The section on implementation is placed at the end of the framework and concerns the sustainability, likelihood of routine adoption, and the feasibility of scaling up the relevant intervention (129). However, the framework's guidance on implementation strategies and evaluation of implementation interventions is limited. When conducting a complex intervention study where implementation is a primary focus, it is therefore useful to complement the framework with implementation science theory and methodology, to identify possible implementation strategies and appropriate study and evaluation designs.

Implementation science is a relatively recent, developing, and rapidly growing field of research, with the overall aim of closing the considerable gap between scientific evidence and clinical practice (107). It may be defined as '…the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care' (136). The recognised need for theoretical and methodological approaches within this new field of study has led to a wide and partly overlapping spectrum of theories, models, and frameworks. Nilsen (137) has created a useful taxonomy of these where he distinguishes between the approaches that aim to describe and/or guide the implementation process (process models), those that focus on evaluating implementation (evaluation frameworks), and the approaches that seek to understand or explain the factors that influence implementation outcomes. The explanatory approaches include classic theories that are borrowed from other disciplines, such as psychology or sociology, implementation theories that derive from within the field itself, and determinant frameworks that specify factors that may influence implementation outcomes (137).

Among the determinant frameworks, perhaps the most influential and widely used is the 'Consolidated Framework for Implementation Research' (CFIR), published in 2009 (138) and updated in 2022 (139). Although categorised as a determinant framework (137, 139), it is

described by its authors as ‘meta-theoretical’, since it constitutes a synthesis of constructs from existing implementation theories (138). The CFIR consists of five domains that can be used to assess, address, and interpret important factors influencing the implementation outcomes of a study. These include characteristics of the innovation/intervention itself; of the outer setting such as the community, hospital system, or state; of the inner setting where the intervention is implemented (e.g. a specific hospital); of individuals that organise, implement, deliver, or receive the intervention, and important factors or stages of the implementation process itself (138, 139). Thus, the CFIR can be said to transcend Nilsen’s (137) taxonomy by describing the implementation process, by synthesising constructs from implementation and classical theories, and by specifying determinant constructs that can be evaluated as part of an implementation study. As a consensus-based and review-based descriptive synthesis, a limitation of the framework is the lack of systematic evidence to support the relative importance of the constructs and the nature and significance of their interrelations. However, the aim of the CFIR was to establish a pragmatic and consistent terminology with clear definitions, from which such evidence and theory could be generated (138).

While the CFIR can be used to assess important contextual factors and inform the choice of implementation strategies, it was beyond its scope to provide a detailed and concrete list of implementation strategies to address these determinants (139). The ‘Expert Recommendations for Implementing Change’ (ERIC) study, on the other hand, published an updated and refined compilation of implementation strategies in 2015 (140). Through three rounds of a modified Delphi process, a panel of experts arrived at a final compilation and description of 73 distinct implementation strategies (140). In the second phase, the expert panel used concept mapping to group the 73 implementation strategies into 9 categories and to rate each strategy’s relative importance and feasibility (141). The ERIC may improve the identification, selection, and reporting of appropriate implementation strategies, but was based on expert consensus and explicitly did not consider the evidence base for each strategy (140).

A second taxonomy of implementation strategies, which was last reviewed and updated in 2015, was developed by the now decommissioned ‘Effective Practice and Organisation of Care’ (EPOC) group at Cochrane (142). The group included 20 implementation strategies, primarily aimed at healthcare workers, as part of a larger classification of health systems interventions (142). Central strategies included ‘Educational outreach visits’, defined by the EPOC as ‘Personal visits by a trained person to health workers in their own settings, to provide information with the aim of changing practice’, and ‘educational meetings’, described as ‘Courses, workshops, conferences or other educational meetings’ (142). The strategy ‘Audit and feedback’ was defined as ‘A summary of health workers’ performance over a specified period of time, given to them in a written, electronic or verbal format. The summary may include recommendations for clinical action’ (142). Audit and feedback is one of the most frequently used strategies within the field of implementation science, where it is commonly part of a ‘formative evaluation’ approach. The latter differs from ‘summative evaluation’ in that process monitoring data are systematically fed back to staff and/or implementation teams during the study, to adapt and improve the implementation strategy and process (107).

The EPOC taxonomy is frequently used to categorise implementation strategies in systematic reviews and meta-analyses. In 2022, an overview of systematic reviews of strategies to implement clinical practice guidelines in public health services, using the EPOC classification, reported that 'care pathways' and 'educational meetings' were generally effective as single strategies, whereas 'audit and feedback' and 'strategies targeting the organisational culture' were generally effective as part of multifaceted strategies, on either process outcomes or professional outcomes (143). A report made jointly by the American Heart Association and American College of Cardiology summarised the available evidence in 2017 on four selected guideline implementation strategies: 'educational outreach visits', 'audit and feedback', 'provider reminders', and 'provider incentives' (144). They found that audit and feedback and educational outreach visits were generally effective in improving both process outcomes and clinical outcomes (144). Although the studies above suggested that some implementation strategies were generally effective, variable methodology, poor reporting, and inconsistent use of terms and concepts precluded more rigorous knowledge synthesis through meta-analyses (143, 144), while also hindering the generation of evidence on potential mediating or moderating mechanisms (145).

After having selected and employed appropriate implementation strategies, an important part of an implementation study is to evaluate these strategies and their impact. Proctor et al. (146) has made a classification of 'implementation outcomes', where the latter is defined as conceptually distinct from 'service system outcomes' and 'clinical treatment outcomes'. Implementation outcomes are used to evaluate the implementation process and effectiveness, while also being key intermediate outcomes for service outcomes and clinical outcomes (146). The implementation outcomes include acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability. I shall return to all of these in the methods and discussion sections of this thesis, and will only introduce 'fidelity' and 'penetration' as part of this overview. Fidelity is a measure of whether the intervention was delivered as intended, i.e. the adherence to an EBP or guideline (146). The rationale of focusing on fidelity is that by replicating the core elements of an intervention, with demonstrated efficacy and/or effectiveness, one may achieve similar effects (147, 148). Fidelity measures were first introduced to standardise the content of psychotherapy models, but the method was quickly adopted to assess model adherence for other EBPs as well (148). When fidelity scores are reported back to service providers through formative evaluation, fidelity assessments may constitute an implementation strategy, in addition to being part of a process evaluation and implementation effectiveness evaluation. While measures of fidelity may be said to rate the quality of service delivery, an essential measure of quantity is the 'penetration' or 'penetration rate'. The latter outcome is a measure of the integration and level of delivery of the intervention, often defined as the number of eligible individuals receiving an intervention divided by the total number of eligible persons (146). Proctor et al.'s classification of implementation outcomes (146) underlines the importance of distinguishing between the implementation intervention and the clinical intervention when considering research questions, study design, outcomes, and effectiveness (107). However, making such a distinction is not always straightforward and it may be difficult or impossible to disentangle the effects of clinical and implementation interventions in an implementation study (149).

Within the traditional research pipeline, conducting an implementation study usually means that clinical intervention effectiveness has been established, and the primary concern is therefore to investigate the effectiveness of implementation strategies. The study may follow the implementation effort of a single site or compare sites and/or implementation strategies, with a randomised or non-randomised design (150). However, an alternative and increasingly used approach is the so-called 'hybrid effectiveness-implementation design', where research on clinical and implementation effectiveness can be combined. There are three main hybrid designs: 1) Testing a clinical intervention while also collecting implementation data. 2) Simultaneous testing of a clinical intervention and an implementation strategy/intervention. 3) Testing an implementation strategy while also collecting clinical data. Each type has its strengths, limitations, and recommended conditions for use (149, 151, 152). Using a hybrid design might speed up the translation of research findings, help identify effective implementation strategies, and generate more useful information for researchers and decision makers (151).

2.2.3. Implementation research in mental health services

While the complex interventions framework and implementation science provide general frameworks and methods for implementation and intervention research, the field of mental health services research adds to these perspectives by operationalising them in the context of mental health care. There is naturally a considerable overlap between general implementation science and implementation research in mental health services, not least because many central implementation theorists and researchers have worked within the field of mental health.

In the previous chapter, we saw how the deinstitutionalisation of mental health services and the evidence-based paradigm led to a change in how professionals viewed relatives and their role in the assessment, treatment, and follow-up of patients with severe mental illness. The establishment of FPE as an EBP was part of a larger move towards evidence-based community mental health services. At the turn of the millennium, the number of well-documented psychosocial EBPs had increased significantly to include FPE, 'Assertive Community Treatment' (ACT), 'Supported Employment' (SE),' Illness Management and Recovery' (IMR), and 'Integrated Dual Disorders Treatment' (IDDT) (39). However, it was generally recognised that few patients and relatives actually received these EBPs, indicating that policy makers, administrators, and researchers had to focus on the systematic implementation of guidelines and EBPs in regular clinical practice (39). This included an adoption and further development of implementation science principles to identify barriers to implementation on multiple levels, but also to recognise potential facilitators and promising implementation strategies (153). Scientific concepts and methods for conducting and evaluating implementation efforts in mental health services had to be developed, being informed by and contributing to implementation science in general (154).

A major contribution to the field was the 'National Evidence-Based Practices' (NEBP) project, launched by the Robert Wood Johnson Foundation to increase the implementation of five psychosocial EBPs in CMHCs in the United States (147). 53 CMHCs across eight states chose

to implement either FPE, ACT, IMR, SE, or IDDT over a two-year period and fidelity to the selected EBP was measured every sixth month throughout the 24-months implementation period, using a non-randomised experimental design (155). The implementation model was developed through conducting a review of the available evidence for implementation interventions; meetings and communication with administrators; focus groups with frontline clinicians; obtaining perspectives and experiences of advocacy groups, and the combined experience of the researchers themselves with similar efforts (12). Toolkits were created for each separate practice and distributed to the relevant sites, containing practice manuals, scientific papers, instructional videos, lectures, and fidelity scales. The project used previously validated fidelity scales for ACT and SE, whereas new scales had to be developed for the remaining EBPs. The scales consisted of items that were rated from 1 to 5, where 1 meant no implementation and 5 meant full implementation and a mean score above 4 constituted adequate implementation. In addition to providing the toolkit, the project's training-consultation model included consultations with administrators on different levels (ensuring management commitment); "kickoff" sessions at each site; practitioner skills training; ongoing consultation, as well as regular and systematic fidelity measurements with tailored onsite feedback. Units were provided with both fidelity scores and a report which described their progress (or lack thereof). The sites were also expected to appoint a steering committee, including the local leaders and other relevant stakeholders, to monitor and adjust the implementation process (147). The evaluation included both qualitative (observation, field notes, and interviews) and quantitative assessments (fidelity scores) (147). In addition to the fidelity scales, measuring the level of implementation of the EBPs, sites were also assessed with the General Organisational Index (GOI) (156) to examine the individualisation, quality improvement, programme philosophy, and penetration rate domains of EBP implementation. The individualisation subscale measured the tailoring of the EBP to the client's needs, whereas the quality improvement subscale monitored important aspects of the implementation process (157). The project showed that 55 % of sites were able to implement EBPs with high fidelity, but the results and dropout rates varied significantly between EBPs (155). Two out of the six sites implementing FPE dropped out and only three of the four remaining sites achieved high fidelity (147).

A review from 2014 (158) identified major initiatives to implement psychosocial EBPs for people with severe mental illness, with a particular emphasis on the strategies that were used. It described how stakeholder meetings, toolkits, training, ongoing consultation, and quality or fidelity monitoring were the most commonly employed strategies and that, among the eleven included studies, the NEBP project had employed the most comprehensive set of strategies (22 of the 23 strategies described). While all the included studies used quality and fidelity monitoring, only one third reported fidelity and/or service user data (158). In the second part of the review (159), the authors used the CFIR actively to identify critical implementation issues within these studies, demonstrating how 30 different constructs from the framework were relevant to interpret the findings. Critical determinants included the complexity, adaptability, cost, and evidence-base of the intervention; the skills, attitudes, values, and identities of providers; the culture, leadership, and resources of the organisation, as well as community needs, policies, and incentives (159). Later efforts to implement a spectrum of EBPs in mental

health care have employed similar strategies to the NEBP project, including toolkits, training and consultation, audit and feedback, and active management involvement (160, 161).

While several studies have reported significant effects of implementation strategies on clinical- and/or implementation outcomes when implementing EBPs, the aggregated evidence to support the effectiveness of specific implementation strategies in mental health services is very limited (162). A Cochrane review from 2016 (163) examined the effect of guideline implementation strategies in specialist mental health care. Only randomised controlled trials with guidelines/EBPs targeting persons with psychotic disorders were included, and implementation strategies were categorised according to the EPOC classification. The authors included 6 studies and were able to perform meta-analysis on just one outcome, due to the significant heterogeneity of the studies. Most results showed no effect, and the quality of the evidence was rated as low to very low, leading the authors to conclude that uncertainty still remains about how to implement guidelines in specialist mental health care (163). A similar review from 2017 (164) included a wider spectrum of study designs and expanded the patient population to all persons with severe mental illness, resulting in a selection of 19 studies. The authors found that the implementation strategies did not alter professionals' adherence to the guidelines and their meta-analysis did not reveal any significant effects on patients' outcomes. However, consistent positive effects across studies suggested that patients' outcomes may nonetheless be positively affected (164). These surprising findings highlight the need for randomised controlled implementation trials in mental health services that measure both implementation and clinical outcomes, while conducting mixed methods process evaluations to explore the connections between guideline adherence and clinical outcomes.

2.2.4. Mixed methods

The value of a mixed methods approach is recognised by the complex interventions framework, by implementation science frameworks, and within mental health services research (165-168). Combining qualitative and quantitative methods within the same overall study is an increasingly common practice, but the development of mixed methods theory and methodology can still be considered a work in progress. Some critics maintain that the ontological and epistemological assumptions of qualitative and quantitative paradigms are incompatible and therefore should be kept separate. The proponents of a mixed methods approach may be regarded as more pragmatically oriented, emphasising how a mixed methods study may benefit from the strengths of both methods while offsetting their respective weaknesses through complementarity, thus enhancing the overall credibility of the study (165, 169). In a manner similar to the hybrid designs described previously, where clinical effectiveness and implementation strategies are investigated at the same time, mixed methods study designs are frequently used to answer exploratory and confirmatory research questions simultaneously (166).

There are several important considerations when planning a mixed methods study. These include whether the research questions should be separate, combined, or both; the scope of integration between the sub-studies; their relative priority; their timing and coordination, and how and when the sub-studies will be mixed. Depending on the choices made, a mixed methods

study design can be described as having a convergent, explanatory sequential, or exploratory sequential design, according to Creswell and Plano Clark (170). It is necessary to integrate the qualitative and quantitative findings when conducting a mixed methods study, or it will rather become a 'multi-method' or parallel study (166).

When researching complex interventions, a central advantage of a mixed methods approach is how it may foster incremental knowledge. This type of knowledge-generation is achieved when findings from the methodologically different sub-studies inform each other in a stepwise fashion through feedback loops, which also allows for a continuous development and refinement of the research question(s) (165). Within the field of general implementation science, mixed methods are often used to identify barriers and facilitators, to develop implementation and sustainability strategies, and to monitor the implementation process (166). The overall benefits of employing qualitative methods in mental health services and implementation research include an increased depth of understanding; being able to elicit the perspectives of study participants; exploring less studied issues; developing concepts and hypotheses, and conducting process evaluations (168). Mixed methods may be particularly suited to study recovery-based interventions in mental health, such as FPE, where both clinical (objective) and personal (subjective) recovery need to be investigated (171).

2.2.5. Stakeholder engagement

Stakeholder engagement is an integrated part of the complex interventions framework (129, 130) and implementation science frameworks such as CFIR (138, 139). It is also frequently used within mental health services research, since it is highly compatible with the recovery paradigm and increasing emphasis on patient autonomy (172).

'Participatory action research' (PAR) is a recent and increasingly used approach that emphasises continuous and pervasive stakeholder involvement. PAR usually employs qualitative or mixed methods, inspired by paradigms such as constructivism and critical theory. The approach explicitly seeks to empower study participants and provide an alternative to 'classical' epidemiological and health services research (173). A similar approach is that of responsive evaluation, which aims to make stakeholders active and equal partners when designing and conducting evaluations of health interventions, recognising that there may be different values and interests that need to be negotiated to generate a mutual understanding or consensus (174). While these approaches' grounding in postmodern or constructivist paradigms may seem incompatible with the assumptions of randomised controlled trials or epidemiological studies, they may nonetheless be used to complement or inspire such research efforts. By employing similarly comprehensive and continuous stakeholder engagement, rigorously designed studies may formulate research questions, develop interventions, and select outcomes that are relevant to and address the needs of service providers, patients, and relatives.

2.3. Implementation of family involvement in mental health services

In this chapter, I will first describe the scientific literature on facilitators for implementing family involvement in mental health care, followed by an overview of studies on the implementation of family involvement in mental health services.

2.3.1. Facilitators for implementing family involvement in mental health care

While the barriers to family involvement have been investigated quite extensively, the literature on facilitators is rather sparse. The reviews and studies that have considered facilitators specifically, usually reported these without differentiating between hypothesised and documented effects. Facilitators are often explored together with barriers through qualitative methods, and the results often constitute the informed views of researchers or study participants on how to address the central barriers. As with barriers, there are facilitators at the policy, organisational, and clinical levels, where some may be considered general facilitators for the adoption of EBPs, and others may be more specific to the implementation of family involvement.

Perhaps the most important facilitator at the policy level is to change financial incentives and reimbursement schemes to favour family involvement in mental health services (175). At the organisational level, reported facilitators include leadership commitment support, and prioritisation (1, 3, 4, 9, 57); revising agency procedures and protocols such as intake or employee position descriptions (19, 175); adapting family involvement to the local context (1), and securing additional 'investment' resources (57). Adequate staff training and education is important, but a critical factor is having access to ongoing supervision and support after the training has been completed (1, 3, 4, 9, 19, 57, 113). Another important facilitator is for clinicians to develop skills and experience with family involvement (3, 9). A permanent family coordinator, to oversee and coordinate the unit's family work, may also facilitate the implementation of family involvement (4, 176, 177). To be able to include relatives, who usually have other commitments, an important facilitator is the ability to provide family involvement sessions outside regular working hours, in different locations, and through phone calls and digital communication platforms (1, 3, 4, 9, 19, 113).

Some facilitators address organisational and clinician-related barriers to implementing an unfamiliar practice, when the latter is perceived as being incompatible with established paradigms or working methods. These facilitators are aimed at changing the organisation's culture and working method and include agency-wide education (4, 175, 177), establishing a shared culture of family work (9, 178, 179), and multidisciplinary collaboration where the entire team or unit is involved in delivering family involvement (3, 9). Such a whole-team or whole-ward approach has been employed by studies within mental health (87) and other fields of health services research (180). Using consumers and families to disseminate family involvement practices may also increase the awareness among clinicians, patients, and relatives (1, 4).

At the clinical level, a central facilitator is the adequate timing of family involvement. Initiating family involvement too early when the patient is acutely ill might hamper the process. However, it is even more critical not to start too late, when relatives have become frustrated, tired, and disappointed with the health services (9, 113). It is vital to engage patients actively, by providing them with information about the benefits of family involvement, discussing information sharing, and exploring and addressing their concerns (19). Relatives must also be actively engaged, by providing them with information and establishing a partnership (9, 19). Service providers may facilitate family involvement by tailoring it to the preferences, needs, and context of individual patients and their families, through ongoing assessment (1, 9, 19, 57, 58, 113). They may also provide written information about the family involvement at the unit, and about other resources and support measures (19).

2.3.2. Studies on the implementation of family involvement in mental health services

This overview will be limited to multi-site implementation studies that included clinical interventions similar to those of the IFIP study, for adult persons with severe mental illness, with reported implementation strategies and outcomes, in international English language publications. In the end, I will list a few studies that did not meet these criteria, but that are nonetheless relevant to the IFIP study or to the Norwegian context. With the reservation that this list may not be exhaustive, the studies identified are listed below in sequence according to their year of publication.

Studies published before the IFIP study

In 2001, McFarlane et al. (179) reported from a project implementing multifamily psychoeducation groups in the states of Maine and Illinois, at 66 mental health agencies. The target group of the clinical intervention was not specified, but appears to have been patients with severe mental illness and their relatives. The study design was non-randomised observational, with a naturalistic process evaluation of implementation in the two respective states. The implementation strategies in Maine included a statewide and local consensus-building; ensuring that human, financial, and technical resources were in place, and a four-step implementation design with local needs assessments; continued consensus-building and clinical training; local adaptions, and ongoing supervision and consultation. The strategy in Illinois was similar, but differed in terms of organisational structure and financial incentives, a lesser emphasis on consensus-building, less use of consultation and supervision, less funding allocated to the implementation, as well as having direction from outside the state. The authors reported the number of agencies that had initiated the intervention in each state and predictors in the form of a clinician-reported instrument, where the importance of various barriers and facilitators were rated on Likert scales. 14 of the 15 agencies in Maine initiated at least one group, whereas only 5 of the 51 agencies in Illinois did so. The survey of clinicians' perceptions of barriers and facilitators predicted which sites would succeed in implementing the intervention, where clinicians in Maine were less skeptical towards the intervention and more

interested in receiving supervision and consultation, reflecting a wide-ranging local consensus (179).

In 2004, Gorrell et al. (181) published the results of a retrospective observational file audit of four mental health centres in Northern Sydney, before and after the implementation of Australian national evidence-based guidelines for early psychosis. The implementation strategies included voluntary clinical workshops, as well as the restructuring of services in three centres and the appointment of an early psychosis coordinator in the fourth center. The audit was performed through retrospective chart reviews for patients receiving treatment before (n=47) and after (n=70) the implementation of the guidelines, using an instrument with 27 clinical indicators, including four family involvement indicators. The percentage of patients who had their family attend a meeting at the clinic fell from 78.7 to 72.9 %, whereas the percentage who received FPE rose from 40.4 to 47.1 %. None of these changes were significant when analysed with Chi-square tests. However, the percentage of families that were offered psychoeducative seminars rose from 6.4 to 28.6 % and the percentage of families that actually attended these seminars rose from 2.2 to 12.8 %, where both changes were significant (181).

In 2007, McHugo et al. (155) reported the fidelity outcomes of the NEBP project, followed by a second publication by Bond et al. (147) in 2009, which described the implementation process in more detail. The NEBP project, study design, and implementation strategies have been described in the previous chapter. As one of five psychosocial EBPs for persons with severe mental illness, FPE was implemented in six clinical sites, where two dropped out. Fidelity was measured every 6th month with the FPE fidelity scale (182) and at 24 months the mean score in the four remaining sites was 4.00 with SD 0.58, where three of the sites had reached scores of 4 or above. If one includes all the six sites, only 50 % achieved adequate implementation. Mixed-effects regression models showed a significant practice-by-time interaction during the first year (155). The NEBP project was a major inspiration for the IFIP study.

In 2012, Ruffolo and Capobianco (183) published an account of a U.S. single-state effort to implement multifamily psychoeducation groups for persons with schizophrenia and their families, in 11 regions containing over 30 clinical sites, using the original CFIR framework (138) to analyse the implementation process. The implementation interventions included training and supervision of clinicians, as well as regional EBP implementation teams. Each region initiated at least one FPE group and 73 groups were established in total. Fidelity, assessed with an unspecified patient and relative-reported measure, was generally high. Penetration was not specified but was referred to by the authors as ‘minimal’ (183).

In 2013, Van Duin et al. (160) published the results of a major initiative in the Netherlands to implement six EBPs for persons with schizophrenia in 30 mental healthcare teams, using an experimental cohort design. The implementation strategies included a national expert team and network; using the ‘Plan-Do-Study-Act’ (PDSA) cycle and the ‘Breakthrough method’; clinical training and supervision; audit and feedback; toolkits; active stakeholder involvement and feedback; leadership/management engagement and commitment, and organisational measures. Family interventions (unspecified) were prioritised to be implemented in 8 teams, but their level of implementation was measured in all 30 teams, by a repeated self-assessment survey among team coordinators. During the implementation period, the percentage of teams who offered

family interventions rose from 43 to 60 %, teams with established procedures for family interventions rose from 10 to 27 %, and teams where over 70 % of patients had received family interventions according to protocol rose from 0 to 10% (160).

In 2015, Kealey et al. (184) reported implementation and fidelity outcomes from a project that implemented multifamily psychoeducation groups for persons with severe mental illness in 31 clinical sites in New York State, using a non-randomised experimental design. The implementation strategy was informed by the NEBP project, including clinical training, network meetings, and the constitution of a local implementation team. Implementation teams in 16 sites received monthly consultation in groups of four teams, whereas implementation teams in the 15 remaining sites received individual monthly consultation. Allocation to the consultation format was non-random. The FPE fidelity scale (182) was used to assess fidelity to the intervention via telephone interviews four times during the project, and the authors also recorded the time required to implement key intervention milestones. Intent-to-train analyses, using the last available fidelity scores, gave an overall mean fidelity score of 3.3 and showed that 12 of 31 sites had implemented the intervention with a mean fidelity score of 4 or above. Structural items were generally rated with higher mean fidelity scores than items describing clinical content. Fixed-effects multilevel regression models showed that the scores increased significantly throughout the project. 65 % of sites achieved all three intervention milestones, and for these sites the mean time from training to initiation of the intervention was just under one year. The sites that conducted the first joining session 4-12 months after training were significantly more likely to complete a multifamily group. There were no statistically significant differences in fidelity scores between the groups who received different consultation formats (184).

Studies published after the IFIP study began

In 2021, Ruud et al. (161) published the fidelity outcomes of a cluster randomised trial on the implementation of four EBPs for persons with psychotic disorders in 39 Norwegian mental health clinics. The project was called ‘Bedre PsykoseBehandling’ (BPB) in Norwegian. Each of the clinics chose two of four available EBPs to implement, with 14 sites selecting FPE as one of their practices. Through pairwise randomisation, half of these clinics were allocated to receive intensive support to implement FPE, whereas the other half were allocated to receive implementation support for their other chosen practice. The implementation support included a toolkit; clinical training and supervision for 12 months; systematic regular implementation facilitation by trained implementation facilitators, and audit and feedback through fidelity scores and reports, as well as receiving the results from an online clinician-reported questionnaire (185), assessing their experiences with the implementation process. Fidelity measurements were carried out at baseline and every 6th month throughout the 18-month implementation period, using the FPE fidelity scale (182). Assessments were based on interviews with multiple clinicians and reviews of written material. The mean baseline score was 1.66 for both arms, while at 18 months, the mean fidelity score had risen to 3.31 in the experimental arm, whereas it was 1.85 in the control arm. Three sites in the experimental arm had achieved adequate fidelity, but no sites in the control arm had reached this point. Linear

mixed models (LMMs), comparing experimental and control conditions, yielded no significant differences in increase of fidelity scores over time. Post hoc analyses found no significant increases in either arm over time and no significant differences between them. Two experimental units decided not to implement the practice, but were scored throughout the trial and included in the analyses (161). In the five units that implemented the practice, the mean fidelity score was 4.11 at 18 months (182). The BPB project was a major inspiration for the IFIP study, and Professor Ruud and Dr. Heiervang have been involved in both projects.

In 2021, Browne et al. (186) reported on the implementation of multifamily psychoeducation groups in six early intervention for psychosis programmes in an unspecified U.S. state, using a non-randomised experimental design. The implementation interventions included clinical training and subsequent monthly consultation by phone. A day-long 'booster' session was offered after 9 months, where implementation issues were also addressed. After 15 months, representatives of the local clinicians provided a report for each site, detailing the implementation status, barriers and facilitators encountered, and any local modifications of the intervention. Only four sites reported implementation outcomes, where the mean number of groups conducted was 4.3. Adaptations included minor changes to the content and eligibility criteria of the intervention (186).

Other relevant studies

There have been several international studies on the implementation of family involvement, either individually or as a component of programmes for early-stage psychosis. The RAISE Connection Programme for early psychosis (187, 188) included family involvement practices and measured fidelity to the programme in two U.S. clinical sites. The authors found that 60 % of clients had completed an initial consumer family preference form and that 98% of them had attended at least one meeting with a family member present (188). The GET UP PIANO trial (189) was a major Italian randomised implementation study of a multi-element psychosocial intervention for first-episode psychosis, including family interventions, and mainly reported clinical outcomes. Another large-scale study, reported by Magliano et al. (190), implemented FPE in single-family groups in six different European countries, and monitored barriers and facilitators through a clinician-reported questionnaire at four points during the trial.

Miklowitz and colleagues have developed and studied 'Family-Focused Therapy' (FFT), which is a variant of FPE that can be delivered to persons with psychotic or bipolar disorders and their relatives (54). The researchers have measured and reported on fidelity to the intervention in several studies to assess discriminant validity (191) and predictive validity (192), and to compare the effect of clinical training formats of different intensity (193). They have also explored how the flexibility and structure of the model may act as determinants of successful implementation (194).

Concerning the development of basic and comprehensive family involvement services, the work of Professor Mottaghipour and colleagues from 2006 (177) deserves a special mention. In the Division of Mental Health at the Sutherland Shire in Sydney, they developed a programme model to implement family involvement in adult mental health services, employing

continuous stakeholder involvement. The programme included clinical training and supervision; appointing a steering committee; appointment of local coordinators; development of the 'pyramid of family care' model (58); creating communication tools and written information to improve the initial engagement of families with the service; diagnosis-specific psychoeducative seminars for relatives; family consultation sessions, and other measures to increase support for families. The authors reported that clinicians' contact with families were doubled during the 3 year development period (177). Mottaghipour has later contributed to the development of family services for persons with severe mental illness in Iran (195, 196).

In addition to BPB, an important Scandinavian contribution to the field was the Danish OPUS trial (197), where multifamily psychoeducation groups were implemented as part of early intervention services from 1998 to 2000, in Copenhagen and Aarhus counties. Another central study was the 'Treatment and Intervention in Psychosis' (TIPS) project (198), which implemented multifamily psychoeducation groups, in three Norwegian and one Danish health care sector from 1997 to 2000. The OPUS and TIPS projects focused mainly on clinical outcomes. An even earlier study from 1994, 'The Psychosis project' (199), studied the effect and cost-effectiveness of FPE in a Norwegian sample of persons with early-phase schizophrenia. Finally, a project in southern Norway studied how to improve practices for collaboration with relatives in a mental hospital (200), whereas another Norwegian study has evaluated clinicians' experiences with the Family-Centered Support Conversation Intervention based on the Calgary model (201). Both studies employed qualitative methods.

2.4. Summary of knowledge gaps relevant to this thesis

Before introducing the IFIP study, a summary of relevant knowledge gaps from the background section may be helpful. At the beginning of the study, in 2017:

- We had little knowledge about the level of implementation of the national guidelines on family involvement for persons with psychotic disorders in Norwegian CMHCs, but preliminary mapping indicated that the level was generally low.
- No studies, to our knowledge, had measured the implementation of family involvement practices for persons with psychotic disorders systematically and comprehensively in mental health services. Previous studies had only measured the implementation of specific family interventions or a few selected basic family involvement practices.
- No fidelity instrument existed to measure basic family involvement practices comprehensively in mental health services.
- No cluster randomised studies had demonstrated a significant increase in fidelity to the FPE model for persons with psychotic disorders, with adequate fidelity in all the experimental sites.
- The research literature provided extensive knowledge regarding barriers to implementation, but the knowledge on effective facilitators and implementation strategies was more limited.
- Few studies had investigated clinicians' perceptions of the benefits of family involvement for persons with psychotic disorders.
- No studies, to our knowledge, had employed qualitative methods to explore the combination of basic and advanced levels of family involvement for persons with psychotic disorders.
- The effects of family interventions for persons with psychotic disorders were well documented, but potential mediators, critical elements, and processes were less investigated.

3. Aims and research questions

3.1. Aims

The overarching objective of the IFIP study was to improve the cooperation between patient, relative, and clinician, as well as the psychosocial health of patients and their adult relatives, by implementing the national guidelines on family involvement for persons with psychotic disorders in Norwegian CMHCs. To achieve this aim, the project group developed and employed a comprehensive implementation support programme (ISP) and a multilevel complex intervention, which were evaluated through a hybrid effectiveness-implementation cluster randomised and mixed methods design.

The purpose of this thesis was to provide an overview of the IFIP study (Article 1), to describe and evaluate the implementation process with quantitative methods (Articles 2 and 3), and to explore clinicians' perceptions of family involvement through qualitative methods (Article 4).

3.2. Research questions

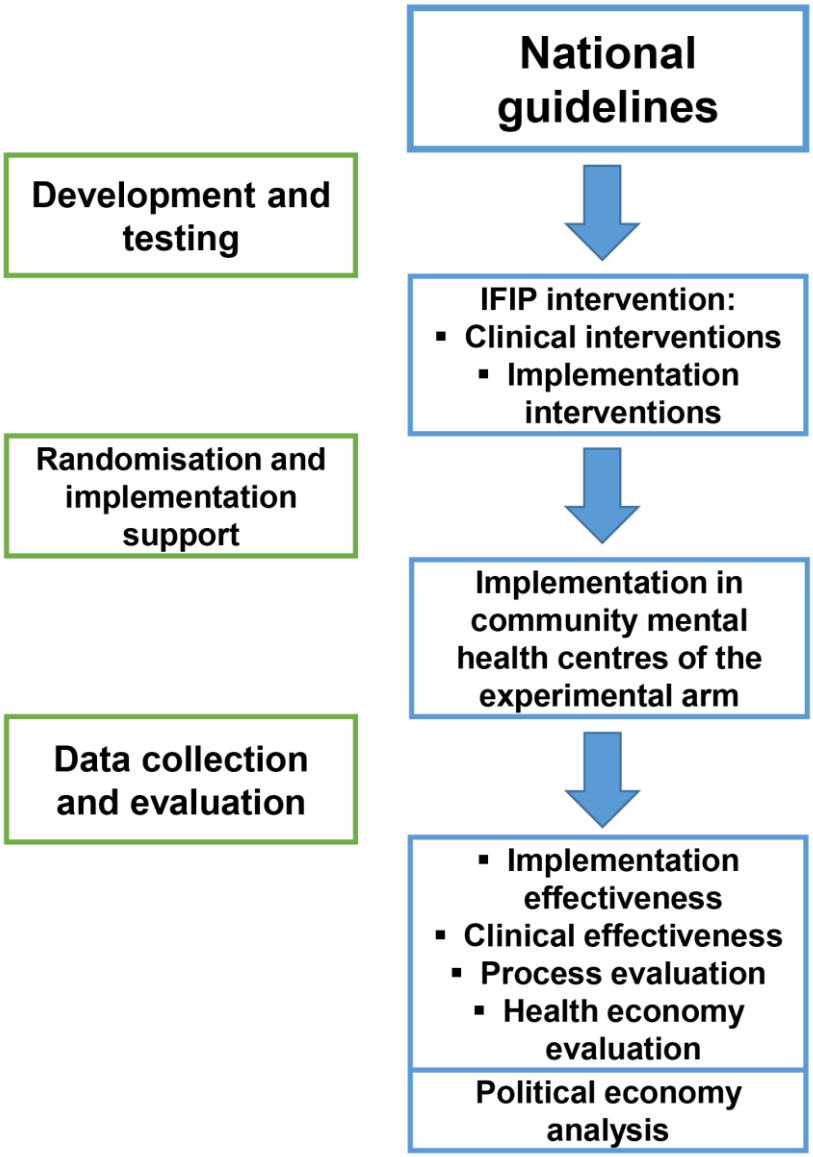
The articles included in this thesis aimed to answer the following research questions:

1. What was the baseline level of implementation of the national guidelines on family involvement for persons with psychotic disorders in participating CMHCs? (Article 2)
2. Did a comprehensive ISP increase the level of implementation of the national guidelines, compared with no such support? (Article 3)
3. How did mental health professionals experience using family involvement in the treatment of persons with psychotic disorders, regarding perceived benefits and disadvantages for patients, relatives, and clinicians? (Article 4)

4. Methods

In this section, I will describe the general study and evaluation design of the IFIP study, account for the present thesis' place within the larger trial, and describe the designs and methods of the included articles. I will describe our methodological choices and how various frameworks were used to inform these, whereas the discussion section will address relevant questions, strengths, and limitations related to our methodological approach. At this point, I would highly recommend the reader to go through the four articles constituting the core of this thesis, in chronological order.

FIGURE 1. OVERVIEW OF THE IFIP STUDY.



4.1. The IFIP study

Figure 1 shows the overall course of the IFIP study from guidelines to interventions, to implementation and evaluation. The phases are similar to those described in the MRC's complex interventions framework from 2008 (130). However, a central difference is that implementation and clinical effectiveness were investigated and evaluated simultaneously in a hybrid design (151), rather than testing clinical effectiveness first and then considering implementation. The IFIP study involved the creation of both a multilevel complex intervention and a multilevel evaluation design, using stakeholder engagement and mixed methods systematically throughout the trial. To complement the IFIP study, with its interventions and evaluations at the clinical and organisational levels, the study also included a political economy analysis to explore barriers and facilitators for implementing family involvement on a sociocultural, institutional, and political level, through qualitative methods.

4.1.1. Trial design, sample size, participating units, and allocation

The IFIP study used a cluster randomised controlled design (202), to be able to analyse differences in implementation outcomes between the experimental and control conditions, and to counteract contamination of the study on patients and relatives' outcomes. We defined a cluster as one or more CMHC outpatient units with the main responsibility for long-term treatment of persons with psychotic disorders, in a discrete catchment area. In accordance with the trials' pragmatic character, there were no other eligibility criteria for clusters.

Sample size was calculated by assuming a mean difference in fidelity scores of 1.82 with a standard deviation (SD) of 0.80, after 18 months of implementation support. These numbers were based on the FPE fidelity scale results from previous studies that employed similar implementation support measures (155, 184). For a two-sided Independent samples t-test, using a 5% significance level and 80% power, we estimated that four clusters in each arm were necessary to show that implementation support leads to a significant increase in fidelity. To ensure adequate power when assessing patients and relatives' outcomes, we calculated that a minimum of seven clusters in each arm were required, when considering the number of eligible participants per cluster and assuming an intraclass correlation coefficient (ICC) of 0.05.

We approached all the 16 CMHCs in five counties of the South-Eastern Norway Regional Health Authority and invited them to participate in the trial, during the summer and fall of 2018. 15 clinical sites from 12 CMHCs in 6 health trusts were recruited, which together serve nearly 25 % of the Norwegian population. The CMHCs that refused to participate, mainly owed their decision to a lack of resources and capacity to engage in a research project. Table 1 in Article 2 provides an overview of the participating clinical sites, which varied highly in terms of service type and patient population. We recruited dual diagnosis teams, assertive outreach teams, early intervention units, and general or specialised outpatient clinics. Some of these exclusively served persons with psychotic disorders, while others had a mixed patient population with recently diagnosed and/or chronic illness. The sample included both rural and urban sites and the populations in their catchment areas showed considerable differences in size, ethnic composition, and median income level.

To get an even number of clusters for allocation, the two sites who collaborated the most were merged, resulting in a total of 14 clusters. The project group used the clusters' baseline number of patients with psychotic disorders as a stratifying variable, generating the following three strata: 4 clusters with 130-217 patients, 6 clusters with 60-129 patients, and 4 clusters with 1-59 patients. Within each block, the clusters were then randomised to the experimental or control conditions with an allocation ratio of 1:1. The allocation was performed by an independent statistician, who was blind to both the sequence of units and the stratifying variable, by drawing 14 numbers with the Microsoft Excel RAND function. Through stratified randomisation, we intended to create a balance between the arms in terms of eligible participants and cluster size, but it also gave us a mixture of urban and rural clusters in each arm. Figure 1 in Article 3 provides a flow diagram of the clusters through recruitment, allocation, and analysis. After the randomisation, the experimental clusters received the ISP for 18 months to implement recommendations from the national guidelines, whereas the control clusters received training and support after the 18 months period. The control conditions may be described as 'implementation as usual' (150), since the control clusters had access to the relevant guidelines and manuals, and were expected to implement them by the national health authorities.

4.1.2. The IFIP intervention and the implementation support programme (ISP)

The project group used the 2008 version of the complex interventions framework (130) actively during the development and feasibility assessment of the IFIP intervention. The 2009 version of the CFIR framework (138) was consulted to identify relevant determinants of successful implementation, but did not have a decisive influence on our final choice of strategies and interventions. While not employing any particular process model to guide the implementation, we did perform a preliminary mapping of barriers and potential facilitators, which is recommended by many such models (137).

Figure 2 in Article 3 illustrates the IFIP intervention and the ISP, which might be helpful to get an overview and to understand the terminology used. We have distinguished between implementation strategies, which include our overall approaches to implementation, and implementation interventions, which are generally more concrete onsite measures. However, if we consult the ERIC and EPOC taxonomies (140, 142), both interventions and strategies could probably have been labeled implementation strategies for conceptual clarity. The implementation interventions and the clinical interventions together formed the IFIP intervention, whereas the combination of implementation interventions and strategies was referred to as the ISP. This might seem like an unnecessarily complicated model, but the main reason for the division was that the national guidelines on family involvement contained recommendations on both organisational/implementation interventions and clinical interventions. Reflecting the national guidelines, the IFIP intervention also included implementation and clinical interventions, and we measured fidelity to both types of interventions during the trial. The ISP constituted the sum of implementation strategies and interventions, intended to support the implementation of the clinical interventions.

The IFIP intervention should certainly be regarded as a complex intervention (130) with a substantial number of components; targeting a wide spectrum of behaviours; requiring expertise and skills among those delivering and receiving the intervention, and targeting administrators, clinicians, patients, and relatives through a multilevel implementation strategy. To accurately describe its development, it might be helpful to regard the IFIP intervention as consisting of two complex interventions: a complex implementation intervention and a complex clinical intervention. The clinical intervention is further made up of two psychosocial interventions that might be considered complex interventions in themselves.

FIGURE 2. DEVELOPMENT AND CONTENT OF THE IFIP INTERVENTION.

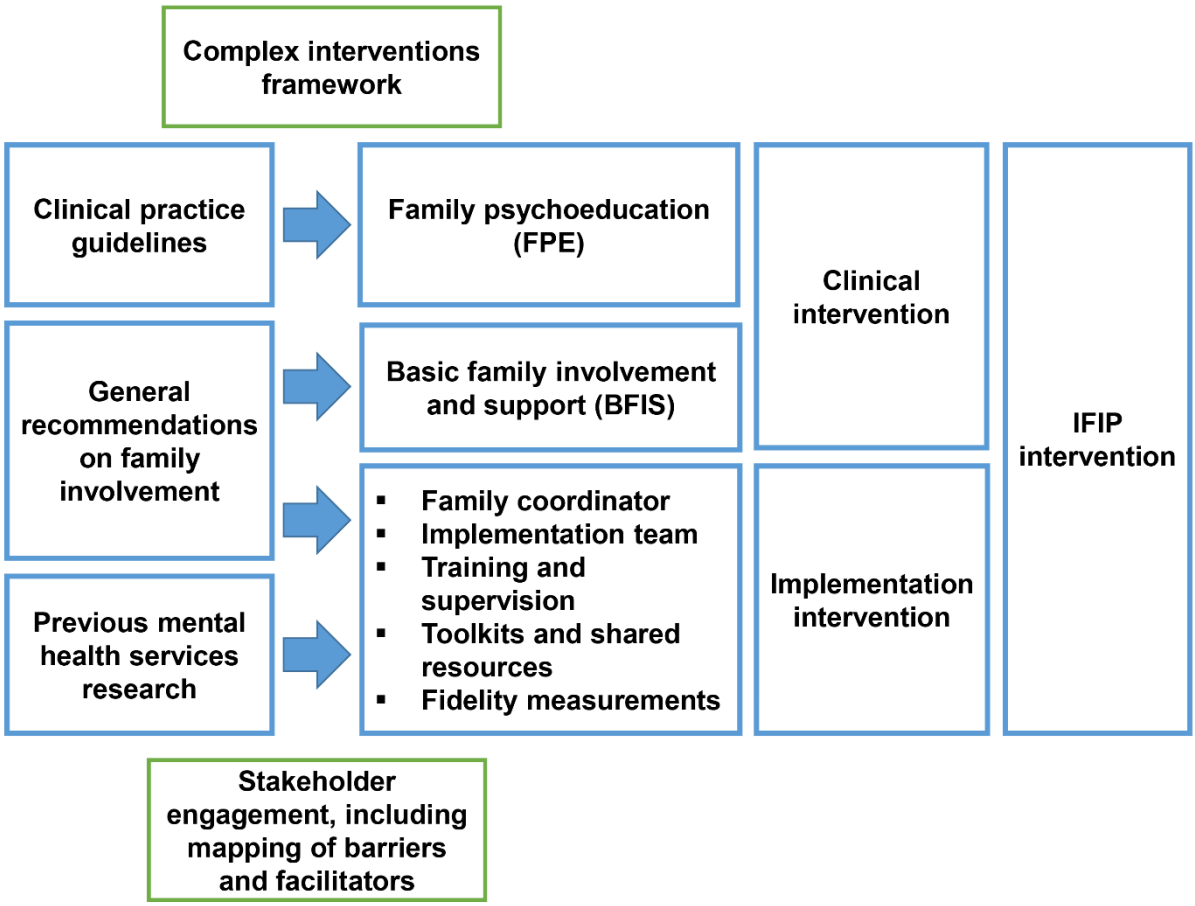


Figure 2 describes the development and content of the IFIP intervention. At the beginning of the study, the project group reviewed the national guidelines on family involvement in mental health care. We chose to narrow the scope of the study to family involvement for adult relatives, recognising that children as next of kin had been a major focus within Norwegian mental health services for several years. The original research proposal was to implement the general recommendations on family involvement (10) in the treatment of persons with severe mental illness, but after careful consideration of the available evidence and potential acceptability (see below), a decision was made to focus on persons with psychotic disorders and to include the relevant clinical practice guidelines (11). In this thesis, I will refer to the general recommendations and the clinical practice guidelines collectively as 'the national guidelines'. The project group selected recommendations from the national guidelines according to the

following non-ranked criteria: a) scientific evidence of relevant and favourable outcomes for patients, relatives, and the public health and welfare services; b) legal regulations and requirements; c) feasibility for the mental health services, and d) acceptability and relevance to patients, relatives, and clinicians.

While the clinical practice guidelines (11) were specific to the treatment of persons with psychotic disorders in specialist mental health services, the general recommendations on family involvement and support (10) applied to all the health and care services. The latter therefore had to be adapted and operationalised to fit the target group and health service setting. Clinical recommendations were condensed to form a clinical intervention called 'Basic family involvement and support' (BFIS), whereas organisational recommendations, such as the appointment of a family coordinator and training and supervision, were included in the implementation intervention. The latter was supplemented with measures from the NEBP (147, 155) and BPB (161) projects, and both implementation interventions and strategies were informed by the scientific literature on barriers and facilitators. However, we did not consult implementation strategy taxonomies, such as the ERIC (140) and the EPOC (142), during the development phase.

The latest meta-analyses on the effects of family interventions (6, 7) were not available to us at the time, but there was nonetheless considerable evidence in favour of family interventions in general and FPE in particular. The evidence was particularly strong with regards to patients with psychotic disorders, where the clinical practice guidelines recommended FPE specifically as a cornerstone of psychosis treatment (11). Since FPE was an EBP that was highly compatible with other established psychosocial interventions, psychotherapy, and medication, we hypothesised that administrators and clinicians would consider implementing BFIS and FPE together more acceptable than implementing BFIS alone. We opted for single-family psychoeducation rather than the multifamily format, because it was considered more feasible for the health services. Appropriate outcome measures for patients and relatives were selected in conjunction with the development of the clinical interventions through an interactive process, by modeling process and outcomes (203).

To assess the appropriateness, acceptability, feasibility, and relevance of the IFIP intervention, the project group recruited three panel groups of 3-9 participants, where separate groups represented patients, relatives, and clinicians. Semi-structured qualitative focus groups were carried out, where the stakeholder panel groups were asked to comment on the proposed interventions of the study. The panel groups also contributed to the preliminary mapping of barriers and potential facilitators. According to Proctor et al.'s taxonomy of implementation outcomes (146), 'appropriateness' is the perceived fit, utility, and suitability of a given clinical intervention, whereas 'feasibility' refers to its actual fit, utility, and suitability and whether it can be successfully used within a specific context. The term 'acceptability' overlaps somewhat with appropriateness, but describes providers' general perceptions of and satisfaction with the intervention itself without considering the context (146). In this sense, one might argue that we assessed appropriateness and acceptability during this development phase, rather than feasibility. However, several of the stakeholders had previous experience with implementing and/or conducting family involvement, making it possible to explore the feasibility of the IFIP

intervention. We further appointed an advisory board, consisting of stakeholder representatives and researchers, who were also given the opportunity to provide input on the intervention and on barriers and potential facilitators. Administrators and key personnel from the participating units reviewed and commented on the same elements. Due to time constraints and limited resources, this simple exploration of feasibility (204) was carried out rather than a full-scale pilot. We therefore had to rely on the experiences from the BPB project with implementing FPE and using a similar ISP and evaluation design in the Norwegian context (161). Systematic stakeholder engagement was employed throughout the trial, inspired by a responsive evaluation approach (174), with continuous feedback from administrators and personnel at the clinical sites; qualitative interviews with patients, relatives, and clinicians, and ongoing assessment of barriers and facilitators.

The major changes that resulted from the preliminary investigation of feasibility, appropriateness, acceptability, barriers, and potential facilitators concerned the implementation strategies and how we perceived the clinical interventions. We became aware that a central barrier to implementation was a lack of shared understanding and appreciation of the importance of family involvement in the treatment of persons with psychotic disorders (205). Personnel with FPE competence reported that training and supervision of a few persons within each clinical unit usually resulted in the other clinicians thinking that family involvement was a special interest, and/or the domain of a specific professional group, rather than a unit-wide concern. These considerations led to our adoption of a whole-ward approach (180), recommending that all clinical personnel should receive training and supervision in FPE and BFIS, for them to offer BFIS to all patients and relatives, and FPE to as many of them as possible. This combination of basic and advanced family involvement practices resembled the principles of the pyramid of family care (58). Through our mapping of barriers and facilitators, we realised that the engagement phase of family involvement was critical, and that clinicians were reluctant to involve relatives because they lacked skills and experience with basic family involvement (205, 206). Thus, the combination of BFIS and FPE not only became a measure to increase acceptability and facilitate the recruitment of clinical units, but also an implementation strategy, where learning and providing basic family involvement became a steppingstone for being able to practice and offer FPE.

The IFIP intervention and the ISP was described in detail in Articles 1 and 3 and partly in Article 2, where table 2 offered an overview of the key elements of the BFIS scale/intervention with references. The rationale and content of FPE has been accounted for in chapter 1 of this thesis, and the structure and content of FPE in single-family groups was reported in Article 1. However, since a major aim of this thesis was to evaluate the process and effect of the ISP, I have included a comprehensive list of our implementation strategies categorised according to the ERIC (140) and EPOC (142) taxonomies. Some of these strategies were not described in the articles of this thesis. As seen in table 1, we employed 36 of the 73 implementation strategies listed in the ERIC compilation and 15 of the 20 implementation strategies of the EPOC taxonomy.

TABLE 1. THE IFIP IMPLEMENTATION STRATEGIES.

	IFIP Implementation strategies	ERIC (140)	EPOC (142)
1	Mapping of barriers and facilitators. Explorations of acceptability, appropriateness, relevance, and feasibility.	Assess for readiness and identify barriers and facilitators	
2	Regular fidelity measurements with onsite tailored feedback and implementation support, during supervision and training days.	Audit and provide feedback	Audit and feedback
3	Cooperation with the R&D departments at Ahus and Vestre Viken Hospital Trust, TIPS South-East (providing FPE training and supervision), and stakeholder organisations.	Build a coalition	
4	Through fidelity visits and qualitative interviews, we collected examples of successful practices, tools, and measures from the units and shared them with the other units, during supervision and training days and network conferences.	Capture and share local knowledge	
5	Kick-off sessions and supervision and training days targeting administrators, implementation teams, and providers. Psychoeducative seminars for relatives where family involvement was one of the topics.	Conduct educational meetings	Educational meetings
6	Kick-off sessions and supervision and training days targeting administrators, implementation teams, and providers, including visits by FPE- and implementation experts.	Conduct educational outreach visits	Educational outreach visits
7	Explorations of acceptability, appropriateness, relevance, and feasibility. Systematic and continuous stakeholder engagement.	Conduct local consensus discussions	Local consensus processes
8	Baseline fidelity measurements.	Conduct local needs assessment	
9	Four days intensive FPE course with supervision every 6th week and refresher training after 1 year. Open line to FPE experts for ad hoc consultation.	Conduct ongoing training	Educational meetings
10	Network conferences and shared resources across experimental sites.	Create a learning collaborative	Communities of practice
11	The project was led by the University of Oslo, collaborating with researchers at Ahus, OsloMet, and Vestre Viken Hospital Trust.	Develop academic partnerships	
12	Development of the BFIS scale to measure the implementation of the national recommendations on family involvement.	Develop and implement tools for quality monitoring	
13	Regular fidelity measurements with onsite tailored feedback and implementation support.	Develop and organise quality	Monitoring the performance of

	Measurement of quantitative outcomes for patients and relatives.	monitoring systems	the delivery of health care
14	Development of a toolkit, including the development of educational material.	Develop educational materials	Educational materials
15	Partnering with TIPS South-East for early intervention in psychosis, for them to provide training and supervision resources.	Develop resource sharing agreements	
16	All the experimental units received the toolkit, including guidelines, manuals, didactic resources, fidelity instruments, barriers- and facilitators guide, and other tools.	Distribute educational materials	Educational materials
17	Each clinical site had a regular contact person from the project group, aiming to build a supportive relationship with the local administration and implementation team, to provide systematic implementation support.	Facilitation	
18	Each clinical site appointed a family coordinator to help implement, coordinate, and sustain the practice. These were often early adopters (see below) and particularly dedicated personnel.	Identify and prepare champions	
19	During the recruitment, development, and planning phases, we identified early adopters at the units who contributed to the preliminary mapping of barriers and facilitators, and who were frequently given a central role in the subsequent implementation effort.	Identify early adopters	
20	Development of a conversation guide for clinicians with questions and strategies to address patients' refusal to initiate family involvement, with problem-solving based on identified clinical barriers, aiming to increase adherence.	Intervene with patients/consumers to enhance uptake and adherence	Patient-mediated interventions
21	Meetings conducted with the Board of directors and/or central administration of various participating health trusts and CMHCs, to ensure commitment to the implementation effort and to share implementation data.	Involve executive boards	
22	Panel groups of patients and relatives to assess the acceptability, appropriateness, relevance, and feasibility of interventions and to map barriers and facilitators pre-trial. Inclusion of user and/or family representatives as members of the local implementation teams. Engagement of local service user boards and peer specialists.	Involve patients/consumers and family members	
23	Interactive FPE course with clinical simulation. Interactive training and	Make training dynamic	

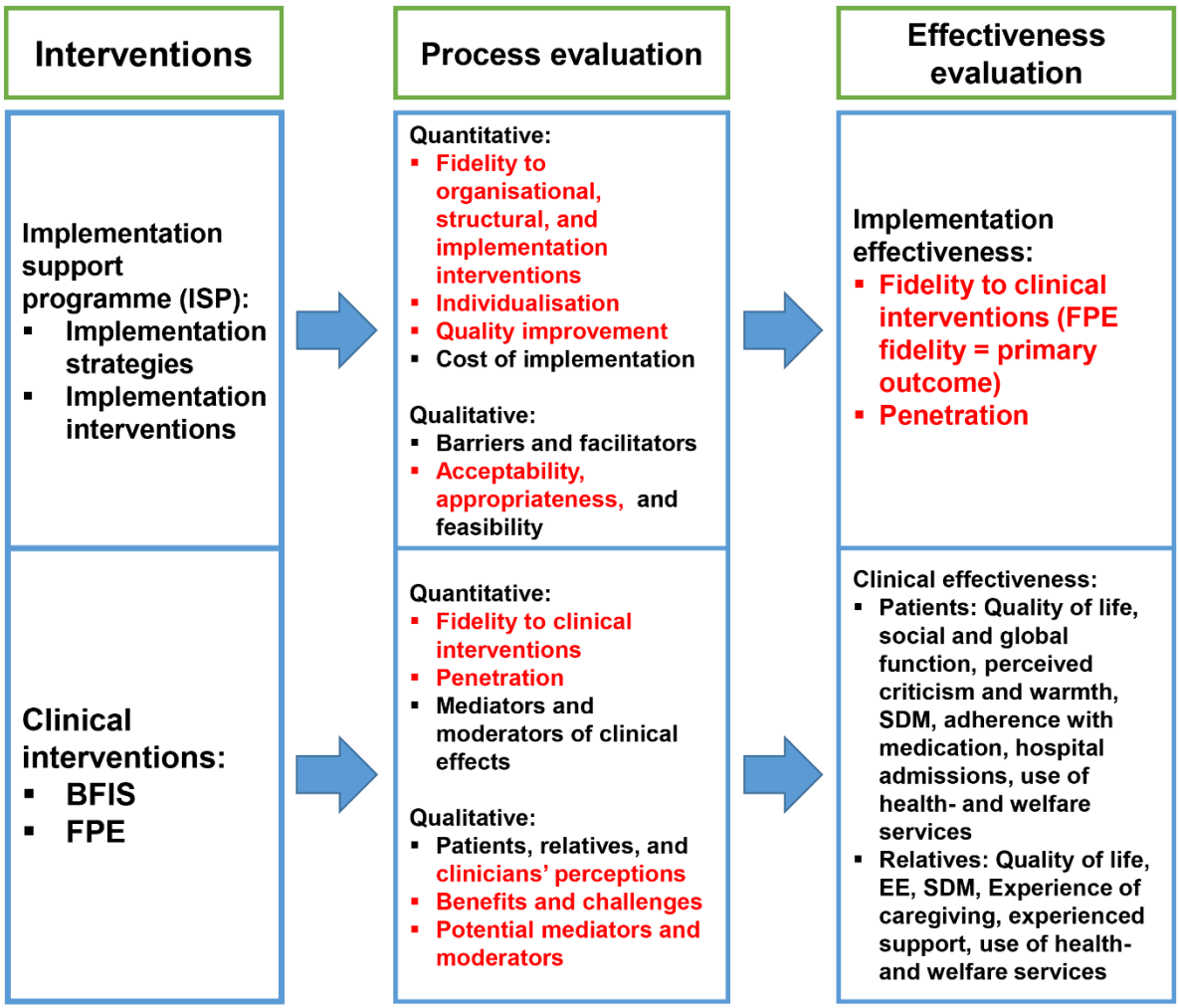
	supervision days, for instance with case-based teaching on how to handle the duty of confidentiality. Videos, films, and web-based resources in addition to written material.		
24	Systematic leadership engagement from the recruitment phase and throughout the trial, to ensure commitment and support. Inclusion of leaders in implementation teams, network conferences, and supervision and training days, with systematic feedback on fidelity results. Implementation support emphasising the importance of the leadership prioritising family involvement, and allocating sufficient staff resources and time for training, supervision, and practice.	Mandate change	
25	Qualitative interviews with patients and relatives investigating the clinical process, significance, and utility of family involvement, as well as challenges. Preliminary findings from these studies were shared with service providers and administrators.	Obtain and use patients/consumers and family feedback	
26	Written contracts of project participation were signed between the University of Oslo and all the partners, including the participating health trusts and CMHCs.	Obtain formal commitments	
27	Each unit constituted a local implementation team to plan and supervise the implementation process, with assistance from project members. Other clinicians had the possibility to reflect on the implementation process during the plenary sessions of the implementation and supervision days.	Organise clinician implementation team meetings	Continuous quality improvement
28	Flexible approach, where local implementation teams and clinicians chose which areas of poor fidelity to focus on. Allowing clinicians to use single elements from FPE without providing the entire model. Emphasising the importance of offering BFIS to all patients and relatives, without necessarily progressing to FPE. Letting clinical units develop their own procedures on family involvement, as long as they covered the main elements of the IFIP intervention.	Promote adaptability	Local consensus processes
29	Network conferences were held three times during the implementation period, where administrators, family coordinators, and implementation teams would share experiences and strengthen their family involvement network.	Promote network weaving	

30	Clinical supervision every 6th week provided by TIPS South-East. Some family coordinators were trained to offer local clinical supervision independently.	Provide clinical supervision	Managerial supervision
31	Implementation consultation provided by the clinical unit's regular contact person within the project team.	Provide ongoing consultation	
32	Continuous feedback from administrators, family coordinators, service providers, and implementation teams was used to adjust the implementation strategy. Fidelity results were used actively by local implementation teams to adjust the local implementation process.	Purposely reexamine the implementation	
33	Development of a conversation guide, to remind clinicians of important topics, as well as relevant phrases and questions when discussing family involvement with patients and relatives. Including family involvement in standardised patient record templates, such as admissions notes, treatment plans, and discharge reports.	Remind clinicians	Reminders
34	Preliminary mapping of barriers and facilitators used actively to develop the implementation strategies and IFIP intervention.	Tailor strategies	Tailored interventions
35	The project appointed an advisory board, consisting of central stakeholders and researchers, to provide input throughout the trial.	Use advisory boards and workgroups	
36	The project group was inspired by the implementation of family involvement at several clinical sites, when developing the IFIP intervention.	Visit other sites	
37	The whole-ward approach was a strategy to alter the organisational culture, by recommending that all clinicians receive training and supervision, and that they offer BFIS to all patients and their relatives.		Organisational culture
38	The overall aim of the project was to implement the national guidelines on family involvement, and the guidelines were used systematically to develop the IFIP intervention and to legitimise the change of practice among clinicians and administrators.		Clinical practice guidelines
39	Through a whole-ward approach, we trained all clinicians, regardless of professional background, in the FPE model and BFIS.		Inter-professional education

4.1.3. Evaluation and outcomes

In the previous subchapter, describing the IFIP intervention and the ISP, we saw how the IFIP intervention can be divided into several complex interventions. For the purposes of evaluation of the IFIP study however, the most critical distinction is between the ISP (implementation strategies and interventions) and the clinical interventions. In figure 3, we see how it is possible to distinguish between the evaluation of the clinical interventions and the evaluation of the ISP, and how these can be further divided into process and effectiveness evaluations. The distinction between process and effectiveness variables is not always straightforward, where some outcomes could or should be regarded as both. From figure 3 it also becomes apparent that the IFIP study evaluated both implementation and clinical effectiveness in a hybrid design, while employing both quantitative and qualitative methods in a mixed methods design. The parts that are written in red text are covered by the articles of this thesis.

FIGURE 3. EVALUATION AND OUTCOMES OF THE IFIP STUDY.



The IFIP study used an implementation-effectiveness hybrid design (151), although the project group was not familiar with this particular term at the development stage. Our evaluation design was inspired by the BPB study, which investigated both fidelity at the service level and patient outcomes at the clinical level (161). The IFIP study is probably best described as a type 2 hybrid study, with a simultaneous investigation of implementation and clinical effectiveness (151), where quite substantial resources were dedicated to data collection from patients and relatives. Yet, certain aspects of the design may resemble a type 3 hybrid study, which is characterised by testing implementation effectiveness while collecting clinical data (151), with fidelity being the primary outcome of the IFIP study.

Clinical effectiveness was measured through questionnaires with patient, clinician, and relative-reported outcome measures, as well as registry data. The term 'clinical effectiveness' is used in a broad sense throughout this thesis, to include outcomes such as shared decision making, satisfaction with services, and relatives' outcomes, in addition to more 'traditional' clinical outcomes like patients' symptoms, function, and quality of life. Since the latter sub-study is not the primary concern of this thesis, it will not be described in further detail here, but the reader will get an overview of its design and outcome measures in Article 1. At the time of submitting this thesis, no results were yet published from the clinical effectiveness sub-study.

Concerning the implementation evaluation, we used Proctor et al.'s (146) classification of implementation outcomes actively to ensure that most of the relevant outcomes were covered. As described previously in this chapter, we explored the acceptability, appropriateness, feasibility, and relevance of the IFIP intervention during the development phase. Acceptability, appropriateness, and feasibility were further investigated through the qualitative interviews and focus groups conducted with the various stakeholders who had provided or received the interventions. We did not measure adoption specifically, which Proctor et al. defines as the initial uptake or implementation (146), but the first fidelity measurements post-randomisation might be said to provide a similar insight. Fidelity and the penetration rate were assessed during every fidelity visit, employing the instruments that will be described in the next chapter. We also monitored the cost of implementation with the aim of conducting a cost-effectiveness analysis. While we did not include specific measures of sustainability, the instruments used during fidelity assessments contain items measuring procedures, organisational structures, and integration of family involvement in the relevant clinical unit, which may affect post-trial sustainability. The IFIP study did not employ quantitative measures of feasibility. As seen in figure 3, I have categorised fidelity to and penetration of the clinical interventions as measures of implementation effectiveness, while the remaining implementation outcomes are regarded as part of the implementation process evaluation.

Figure 3 also shows how the process evaluations of the ISP and the clinical interventions involved the use of both qualitative and quantitative methods, in line with the MRC's recommendations, to investigate the implementation, mechanisms of impact, and context of complex interventions (130, 134). The project group obviously measured fidelity during fidelity assessments, but also the 'dose' of the clinical interventions, which the MRC defines as 'the quantity of intervention implemented' or 'how much intervention is delivered' (134, 135). In addition, we measured 'reach' of the clinical interventions as part of the questionnaires

answered by patients, relatives, and clinicians, which the MRC defines as 'the extent to which a target audience comes into contact with the intervention' (135). Both 'reach' and 'dose' correspond roughly to Proctor et al.'s (146) term 'penetration', differing primarily by the level of measurement (i.e. recipient or provider). The implementation process, which the MRC defines as 'the structures, resources, and mechanisms through which delivery is achieved' (135), as well as adaptions to both clinical and implementation interventions, were partly captured by the fidelity measurements and reports and further explored through qualitative focus groups with implementation teams and ordinary clinicians. Clinical mechanisms of impact, in the form of mediators and moderators, will be investigated in the quantitative sub-study on patients' and relatives' outcomes and were explored qualitatively through focus groups and interviews with all the relevant stakeholder groups. The focus groups and interviews were also used to explore 'participant responses to and interactions with the interventions' (134). Important contextual factors affecting implementation of the clinical interventions were explored through the qualitative mapping among clinicians of barriers and facilitators (205), whereas contextual factors that may influence the effect of the clinical interventions were investigated during focus groups and interviews with all the central stakeholders.

As a whole, the IFIP study employed a mixed methods evaluation approach. The project included both quantitative and qualitative methods to be able to answer both explanatory and exploratory (separate) research questions; to conduct a process evaluation in line with the MRC's recommendations; to develop, monitor, and inform the implementation process and strategy, and to capture the experiences and views of all the central stakeholders. Thus, we aimed to benefit from the complementarity of the different methods, to increase the credibility of our findings, and to allow for incremental knowledge production in a multiphase design. However, we did not employ any framework for mixed methods research to plan or design the mixed methods approach. If we use Creswell and Plano Clark's typology of mixed methods designs from 2018 (170), the IFIP study started with an exploratory sequential design where qualitative methods were used to develop and inform the ISP and the IFIP intervention, which were then evaluated quantitatively in terms of implementation and clinical effectiveness. Yet, as part of the process evaluation, qualitative studies were carried out in parallel with the quantitative evaluation and the preliminary findings were used actively to adapt and strengthen the ISP through a continuous feedback loop. Fidelity scores and reports, together with preliminary qualitative findings, informed both the implementation strategy and subsequent qualitative studies. A prominent example was when we identified the handling of the duty of confidentiality as a major barrier to family involvement, resulting in the inclusion of interactive teaching sessions on the duty of confidentiality in the ISP, and a separate qualitative study exploring the subject (206). As such, the study is perhaps best described as having employed an interactive complex experimental mixed methods design, where qualitative methods are employed before and during an intervention that is studied with quantitative methods in an experimental design (207). While the qualitative process evaluations of the ISP and the clinical interventions were meant to complement and deepen our understanding of the quantitative outcomes, the publications of the IFIP study have not employed a convergent analytical design, as defined by Creswell and Plano Clark, where the results of the two methodological strands are merged and interpreted together (170).

4.2. Designs and methods of the thesis

If we return to figure 3, the parts that are written in red text are included in this thesis, which shows its place within the larger evaluation of the IFIP study. The thesis includes large parts of the implementation and clinical process evaluations, as well as the implementation effectiveness evaluation. Table 2 provides an overview of the thesis' articles in terms of design, outcomes/topics, participants, data collection, and analysis.

TABLE 2. THE ARTICLES OF THE THESIS.

Article	Design	Outcomes/topics	Participants	Data collection	Analysis
1	Study protocol	N/A	N/A	N/A	N/A
2	Cross-sectional	* Fidelity * Penetration * Individualisation * Quality improvement	Leaders, clinicians, and resource persons	Fidelity assessments: Structured interviews, reviews of written material and administrat-ive data	Statistical analysis
3	Cluster randomised	* Fidelity * Penetration * Individualisation * Quality improvement	Leaders, clinicians, and resource persons	Fidelity assessments: Structured interviews, reviews of written material and administrat-ive data	Statistical analysis
4	Exploratory qualitative	* Clinicians' experiences * Potential mediators and moderators * (Acceptability and appropriateness)	Implementation team members and ordinary clinicians	8 focus groups with implementat-ion teams and 5 focus groups with ordinary clinicians	Reflexive thematic analysis

4.2.1. Instruments of Articles 2 and 3

The project group used three scales to measure the fidelity to, and penetration and organisation of, family involvement practices in participating CMHCs, thereby assessing their adherence to the national guidelines. Each scale consisted of 12-14 items that were rated from 1 to 5, where 1 signified a complete lack of implementation and 5 meant full implementation. The sum of item scores was divided by the number of items to calculate the average score, where a mean score above 4 equaled adequate implementation for the GOI and FPE scales. The GOI scale was only used to rate the individualisation, quality improvement, program philosophy, and penetration of FPE. Table 3 provides an overview of the three scales, with their respective domains.

TABLE 3. THE INSTRUMENTS OF ARTICLES 2 AND 3.

Scale	**Items /domains**
The Family Psychoeducation (FPE) fidelity scale (Available from Joa et al. (182))	**14 items** Fidelity to the FPE model (Item 7: 'Prodromal signs' was not measured)
The General Organisational Index (GOI) (Available from Heiervang et al. (156))	**12 items** Individualisation of FPE - 5 items Quality improvement of FPE - 5 items Penetration of FPE - 1 item Program philosophy of FPE - 1 item
The Basic Family Involvement and Support (BFIS) scale (Available as supplementary material of Article 2 and appendix 5 of this thesis)	**14 items** ***BFIS-S subscale - Fidelity*** Conversations - 2 items Structure/organisation - 2 items Implementation - 1 item ***BFIS-P subscale - Penetration*** Penetration - 9 items

The FPE fidelity scale has demonstrated acceptable to good psychometric properties in previous studies, including in a Norwegian translation and context during the BPB project. Based on the results from the BPB study, Joa et al. reported an average interrater agreement of 88 %; an ICC of 0.98; a mean Cronbach's alpha (internal consistency) of 0.84; an ability to capture change over time, and a generally high assessor-reported feasibility (182). Kealey et al. has reported an ICC of 0.67 at baseline and 0.95 at the 12, 18, and 24 months measurements, using the same scale (184).

Concerning the GOI scale, Heiervang et al. (156) has analysed its psychometric properties when measured alongside the implementation of IMR in the BPB project. They report an average interrater agreement of 86 %; an ICC of 0.97; a mean Cronbach's alpha of between 0.77 and 0.80 over three time points; a sensitivity to change over time, and an acceptable assessor-reported feasibility (156). Based on data from the NEBP project, including the implementation of all 5 EBPs, Bond et al. reported an ICC of 0.94 for the individualisation subscale and 0.95 for the quality improvement subscale. They also calculated a Cronbach's alpha of 0.77 for

individualisation and 0.79 for quality improvement, and found that both subscales were sensitive to change (157).

The BFIS scale was developed by the project group to be able to assess the clinical sites' adherence to the national recommendations on family involvement (10), as operationalised in the IFIP intervention. Table 2 in Article 2 provides an overview of the scale with key elements, items, and references. We followed the steps that Bond et al. (208) has proposed for developing a fidelity measure, with the exceptions described below. Because of time constraints and limited resources, the scale was not piloted before the baseline measurements. This meant that some items had to be eliminated or changed afterwards, because of overlap or poor specificity, with additional minor changes after the second round of fidelity assessments.

Sub-items of the training and supervision item 1 were reorganised without eliminating content. The requirements of the family coordinators in item 2 were made stricter, demanding them to have written overviews of support measures and barriers and facilitators. Items 3 and 4 contained sub-items measuring the recruitment to FPE, which were eliminated because the subject was also covered by the FPE fidelity scale. The word 'meeting' in the latter items was changed to 'conversation', reflecting how clinical teams performed these conversations in different settings and not just as part of scheduled appointments. Psychoeducative seminars for relatives (item 12) were arranged once a year by most units, whereas the IFIP intervention recommended two seminars a year, but we concluded that it would misrepresent the units' practice if they were to score 1 on this item, and changed it accordingly. After the revision, minor adjustments of the baseline scores were made with information from the fidelity reports, or by conducting follow-up interviews with local personnel where necessary. Only the consensus scores were adjusted, in order not to affect the calculation of interrater reliability, except where the elimination of items changed the individual scores.

As the BFIS scale's name suggests, it measures fidelity to and penetration of the clinical BFIS intervention. However, it also measures fidelity to organisational, structural, and implementation interventions that are necessary to implement and sustain these clinical practices. As such, it covers both the implementation and clinical interventions of the IFIP intervention, apart from FPE. We considered weighting the individual items, but decided instead to emphasise the clinical elements by including both fidelity and multiple penetration rate items, and to let important fidelity sub-items count as two criteria rather than one. The scale generally favours penetration over fidelity, with 9 versus 5 items respectively, underlining the importance of actually reaching patients and relatives with these practices. The project group did not develop a specific data collection protocol for the BFIS scale, but used the data sources and techniques specified in the FPE and GOI protocols.

4.2.2. Article 1

Article 1 is the published study protocol and describes the rationale, aims, research questions, study design, interventions, and multilevel and mixed methods evaluation strategy of the study. It was submitted for publication in January 2020, after the implementation period had started, but before data collection was completed and analysis had begun.

4.2.3. Article 2

The primary objective of Article 2 was to measure and report the baseline level of implementation of the national guidelines on family involvement for persons with psychotic disorders in participating CMHCs. A secondary aim was to introduce and describe the new BFIS scale. The article only reports the baseline measurements, which were carried out before the randomisation of clusters, as a cross-sectional study.

The data collection consisted of fidelity measurements at each of the 15 clinical sites, where trained fidelity assessors measured fidelity, penetration, organisation, quality improvement, and individualisation of family involvement practices. They carried out structured interviews with personnel that had special competence and work tasks related to family involvement, as well as with leaders and regular clinicians. The participants were recruited through purposive sampling for leaders and resource persons, and convenience sampling for regular clinicians.

Triangulation of sources is an important principle during fidelity assessments (148). The main leader of each site was interviewed individually, and the remaining participants were interviewed in groups of 2-5 persons, resulting in 2-4 interviews of 1-1.5 hours length at each site. In addition, the fidelity assessors reviewed written material such as information leaflets, procedures, invitation letters, checklists, and didactic material, while also using administrative data to measure the penetration of FPE. Verbal informed consent was obtained from all participants before the interviews began. At each site, two fidelity assessors scored all items independently, discussing any discrepancies afterwards to reach a consensus score for each item. Only the sites' practices towards patients with psychotic disorders and their relatives were measured. The assessors, and the pairing of them, varied across the sites. In total, there were five researchers measuring fidelity and none of them were employees of the clinical sites. The fidelity assessors wrote a detailed report to complement and elaborate on the information from the scores. Experimental sites received their scores and reports after randomisation, but did not provide feedback that resulted in score adjustments. Control sites did not have access to their scores and reports, to reduce the influence of fidelity assessments on their practice during the trial.

Data analyses were performed using IBM SPSS statistics version 26. The scale data were analysed with descriptive statistics to report item distributions with means, ranges, and SDs, but also the number of sites that had low, adequate, or full implementation of the various items. To calculate the penetration rate of FPE, we divided the number of patients that had received or were receiving FPE with the total number of patients with psychotic disorders currently receiving treatment at the respective site. We calculated the percentage of exact agreement for the BFIS scale items, while the ICCs of individual items and the mean total fidelity were calculated by employing a one-way random effects analysis of variance model for agreement between two assessors. The ICC for the FPE and GOI scales' mean total fidelity were calculated using the same model. Finally, we performed an independent samples Mann-Whitney U test with two-tailed significance level $\alpha = 0.05$, to investigate possible correlation between the BFIS scale scores and whether the sites' offered FPE.

4.2.4. Article 3

The aim of Article 3 was to investigate whether a comprehensive ISP increased the clusters' level of adherence to the national guidelines, compared with no such support. The primary outcome was fidelity to the FPE model, but the remaining scale outcomes were also important to assess the level of adherence. By including all the fidelity measurements of the study, this article reports most of the quantitative process evaluation, as well as the implementation effectiveness evaluation, of the cluster randomised IFIP trial.

A timeline for the experimental clusters can be found as Supplementary file 2 in Article 3. Kickoff sessions and training in the experimental arm began after the randomisation of clusters in January 2019, but the implementation period officially started in May/June with the first round of supervision and training days. Fidelity measurements in the experimental arm were performed at baseline, 12, 18, and 24 months, whereas clusters in the control arm were assessed at baseline and 24 months only. In Articles 1 and 2, the fidelity time points are specified as baseline, 6, 12, and 18 months, where the latter three refer to months after the official start of the implementation period, which was approximately 6 months after the baseline measurements. Fidelity assessors visited the clinical sites at baseline and 12 months, but had to use a video conference platform for some of the measurements at 18 months and all of the measurements at 24 months, on account of the coronavirus pandemic. Fidelity assessments were carried out in the same manner as described for Article 2. The leaders and resource persons interviewed were mostly the same across 4 time points, whereas the groups of regular clinicians varied to a larger extent, with less variation in smaller sites that had fewer clinicians. The two experimental sites that were merged to a single cluster were scored separately at each time point, and their average scores were calculated to produce the cluster scores. Experimental sites continued to receive their scores and reports throughout the trial, whereas the control clusters received their scores and reports after the implementation period. The researchers who measured fidelity also supervised the implementation teams and clinicians during training and supervision days, but clinical training and supervision in FPE was provided by 'The Early Intervention in Psychosis Advisory Unit for Southeast Norway' (TIPS South-East).

Statistical analyses were carried out in IBM SPSS statistics version 28 and STATA version 17. ICCs for each scale's total mean fidelity were calculated using the same model as in Article 2. The difference in change in the primary outcome (FPE fidelity), between the experimental and control arm from baseline to 24 months, was assessed with an Independent samples T-test to report the mean difference with 95% confidence interval (CI), p-value, and effect size (Cohen's d) with 95 % CI. To assess differences in change, between the experimental and control arms on the three scales and the BFIS subscales, LMMs were estimated with random intercepts for clusters and the following fixed effects:

$$y=\beta_0+\beta_1*Group+\beta_2*t_{12}*Group+\beta_3*t_{18}*Group+\beta_2*t_{24}+\beta_5*t_{24}*Group,$$

where t_{12}, t_{18} and t_{24} were dummies for time, Group was dummy for group (0 for control and 1 for experimental group), and t_{12}*Group, t_{18}*Group and t_{24}*Group were interactions between time dummies and group dummy. Differences in change in the penetration rate of FPE were analysed with a tobit regression model for longitudinal data with the same random and fixed

effects, and both LMMs and tobit models were adjusted for the stratification variable to explore possible impacts on the results. Post hoc analyses assessed within-group changes, between-group differences, and between-group differences in changes. We reported observed means and SDs, as well as mean changes and differences with their respective 95% CIs, p-values, and effect sizes (Cohen's d) with 95% CIs, estimated from the regression models. Results with p-values below 0.05 were considered statistically significant.

4.2.5. Article 4

The purpose of Article 4 was to explore how mental health professionals experienced using family involvement in the treatment of persons with psychotic disorders, regarding perceived benefits and disadvantages for patients, relatives, and clinicians, including possible mediating factors and processes, through a nested qualitative design.

Eight focus groups were conducted with the implementation teams during the middle phase of the trial and five focus groups were carried out with ordinary clinicians in the late phase. The implementation teams had taken part in a previous round of focus groups, which was not included as data material for Article 4. Table 2 in Article 4 provides an overview of the participants in terms of sex, age, and professional background. We used a purposive sampling strategy for the focus groups with ordinary clinicians. The local leaders were asked to recruit a group of 3-6 participants with various professional backgrounds, who were not members of the implementation team but who had practiced family involvement for patients with psychotic disorders, including at least one clinician who had provided an entire course of FPE. If possible, the groups should also include clinicians who had expressed skepticism towards family involvement and/or FPE. There was a considerable overlap between the participants in the fidelity assessment interviews and the participants in the focus groups with implementation teams, but the ordinary clinicians had less overlap with fidelity interview participants. All participants provided their written informed consent before taking part in the focus groups.

Semi-structured interview guides were developed by the project group and went through several revisions. The interview guide for the focus groups with implementation teams was developed to complement and follow up on some of the preliminary findings from the previous round of focus groups, but in the second round the implementation teams had experience with the clinical interventions and the ISP that they could share. They were also asked about ethical dilemmas and conflicts of interest. Building on the findings from the implementation team focus groups, the interview guide for ordinary clinicians was designed to explore the same subjects, but investigated challenges related to the duty of confidentiality in more depth. The interview guide was also designed in conjunction with the interview guides for patients and relatives, to ensure that important topics were explored from all the relevant stakeholders' perspectives. Finally, ordinary clinicians were asked about their experiences with the coronavirus pandemic, which began just after the implementation team focus groups were completed. We did not pilot the interview guides or revise them during the process, but their form and content were influenced by our experiences from previous rounds of qualitative data collection. The focus groups lasted for 1-1.5 hours, were audio-recorded, and transcribed verbatim by research assistants. All the

data material was stored and analysed in the University of Oslo's secure database 'Tjenester for Sensitive Data' (TSD).

The NVivo 12 software was used to organise, code, and store the data. We employed reflexive thematic analysis, using a generally inductive realist approach, and following the six steps described by Braun and Clarke: familiarising oneself with the data; generating initial codes; collating the codes into potential themes; reviewing if the themes work in relation to the coded passages and the entire data set; defining and naming themes through ongoing analysis, and writing the report (209, 210). Patterns had to be identified in focus groups with both implementation teams and ordinary clinicians, from more than one cluster, in order to constitute a theme. Preliminary codes, themes, and thematic maps were discussed within the project group, but also with the IFIP study's advisory board, to look for alternative ways of understanding the data material and the preliminary results. A qualitative analysis of patients' experiences with family involvement was conducted in parallel, exploring similar subjects, and the preliminary results were compared to look for similarities between clinicians and patients' perceptions. Thus, we increased the trustworthiness of the study by employing both investigator and data triangulation.

4.2.6. Research standards and ethical approvals

The IFIP study was approved by the Regional Committee for Medical and Health Research Ethics (REC) with registration number 2018/128, and subsequently by the local data protection officers (personvernombud - PVO) at the University of Oslo. It was also reviewed and approved by the local data protection officers at the participating CMHCs. On behalf of the University of Oslo, the principal investigator signed contracts on shared responsibility for data processing with each participating health care trust, to ensure that local data processing was performed in accordance with the 'General Data Protection Regulation' (GDPR). All major modifications to the study and its protocol were reported to and approved by REC, and reported to the local data protection officers. The trial registration at clinicaltrials.gov was updated regularly.

The study was carried out in accordance with the REC approval, the Helsinki Declaration (211), Norwegian research regulations (212, 213), and the research policies at the University of Oslo (214). Informed consent was obtained from all participants, in written form for Article 4 (appendices 1-2) and verbally for Articles 2 and 3. Verbal informed consent was considered sufficient for the fidelity-based studies, since no identifiable personal data was collected, no recordings or transcripts were made, and the only data produced were the fidelity scores and reports. Interview recordings and transcripts from the qualitative focus groups in Article 4 were treated confidentially and stored at the TSD.

5. Summary of the results

5.1. Article 1

Article 1 was a study protocol and did not report any results.

5.2. Article 2

Overall, the results of Article 2 showed how the majority of the participating CMHCs lacked organisational structures, standardisation, and procedures for family involvement for persons with psychotic disorders. The results also demonstrated that, although many sites had skillful resource persons and other clinicians who were able to offer high-quality family involvement, few patients and relatives had received these interventions. Contact with and involvement of relatives seemed to depend on the clinicians' preferences and practice, resulting in generally low levels of adherence to the national guidelines.

The average BFIS scale score was 2.33, with a mean score of 1.68 on the fidelity subscale (BFIS-S) and 2.69 on the penetration subscale (BFIS-P). None of the sites offered annual training to clinicians in family involvement, although most clinicians had access to relevant supervision. Only four sites had appointed a family coordinator for adult relatives, but all of them had procedures and personnel responsible for following up children who were next of kin. The sites routinely identified the patients' next of kin and discussed family involvement with the majority of patients. Only one site handed out written information about their unit's family involvement and just five sites arranged psychoeducative seminars for relatives. The content, structure, and frequency of conversations about family involvement with patients and relatives varied highly between clinicians and sites, as did the use of crisis/coping plans and documentation of family involvement in the discharge reports. We did not find a statistically significant correlation between the BFIS scale scores and whether the site in question offered FPE, but item 13 (documentation in discharge reports) was borderline significant with $p = 0.054$.

Eight of the 15 sites offered FPE to persons with psychotic disorders and their relatives. The seven units who did not offer FPE were scored 1 on all items in the GOI and FPE scales. Fidelity to the FPE model when offered was good, with a mean FPE fidelity scale score of 4.34 among the eight relevant sites, but the penetration rate was low at only 9.4 %. The overall penetration rate across 15 sites was even lower, at 4.2 %, and the mean FPE fidelity score was 2.78. Despite high model fidelity among the eight sites that offered FPE, only four of them had appointed an FPE coordinator and the recruitment of patients and relatives to FPE was generally inadequate. The GOI scores among the sites that offered FPE corroborated these findings, by showing that only one unit routinely performed systematic identification of eligible clients, how only two units had frequent FPE training, and only one unit provided access to supervision in the model. The overall mean GOI score was 1.78, whereas the average score was 2.46 in the sites that offered FPE. Concerning inter-rater reliability (IRR), we calculated an ICC of 0.99 for mean total fidelity of the BFIS scale, 0.93 for the FPE fidelity scale, and 0.96 for the GOI scale.

5.3. Article 3

The results of Article 3 showed a significant effect of the ISP on the level of adherence to the national guidelines in the experimental arm, when compared to no implementation support in the control arm. Mean scores in the experimental clusters reached 4 or higher on all scales at 24 months, indicating adequate to high levels of implementation. The corresponding mean scores in the control arm were all below 3, indicating moderate to low implementation. All the clusters in the experimental arm offered FPE at 24 months, whereas only 2 clusters in the control arm did so. The mean penetration rate of FPE among experimental clusters rose from 6.76 to 12.84 %, whereas it fell from 4.09 to 2.99 % among the control clusters.

The ICC for total mean fidelity was 0.99 for the BFIS scale, FPE fidelity scale, and the GOI scale. Concerning the primary outcome, the mean difference between the arms on the FPE fidelity scale from baseline to 24 months was 2.69 with 95% CI (0.67;4.71), $p = 0.013$, and effect size 1.55 (0.32;2.75). The results from the LMMs showed that the increase in fidelity scores on all scales from baseline to 24 months was significantly larger in experimental clusters than control clusters, with p-values < 0.001. The results from the tobit models showed a significant difference in change in the FPE penetration rate, with $p = 0.01$. Adjustment for the stratification variable did not alter the results of the regression models. Post hoc analyses showed significant changes on all the scales and BFIS subscales between baseline and 12, 18, and 24 months in the experimental arm, whereas the corresponding changes in the control arm were not significant. The differences in changes from baseline to 24 months, when comparing the experimental and control arms, were all significant and the effect sizes varied from 1.00 to 5.40.

Note: The original version of the published article unfortunately contained a mistake in Table 3, which was introduced during formatting. The correct version of Table 3 was published as a correction, which is included in this thesis.

5.4. Article 4

The central finding of Article 4 was that clinicians mainly reported positive experiences with family involvement in the treatment of persons with psychotic disorders, with substantial benefits for patients, relatives, and health professionals. Here I will only provide an overview of the themes identified, and I encourage the reader to examine the results section of the article to understand these themes and their interconnections in depth.

Four main themes were identified as perceived benefits: 1. Family psychoeducation – a concrete framework. 2. Reducing conflict and stress. 3. A triadic understanding, and 4. Being on the same team. While theme 1 concerned clinicians' general perceptions of the FPE model and its structure, the remaining themes (2-4) formed an interconnected triad of mutually reinforcing elements related to the processes and benefits of BFIS and FPE. This triad of benefits was further linked to three important clinician-facilitated sub-themes; a space for relatives' experiences, emotions and needs; a space for patients and relatives to discuss sensitive topics

and, an open line of communication between clinician and relative to ensure continuous support and appropriate follow-up.

Perceived disadvantages or challenges were far less frequent, but we identified the following three main themes: 1. Family psychoeducation – occasional poor model fit or difficulties following the framework. 2. Getting more involved than usual, and 3. Relatives as a potentially negative influence – important nonetheless.

6. Discussion

6.1. Discussion of the methods

In this chapter, I will address central questions, strengths, and limitations related to our methodological approach. First, I will consider the overall study design, interventions, and evaluation design of the IFIP study, before discussing the methods of the thesis and its articles, ontological and epistemological positions, reflexivity, and ethical considerations. Since many of the study's strengths have been accounted for in the methods section, this chapter will to a larger degree focus on limitations, challenges, and important trade-offs.

6.1.1. The overall study design of the IFIP study

The IFIP study was a highly pragmatic enterprise, where the main objective was to achieve successful implementation of the national guidelines. This is reflected in the project group's eclectic use of theoretical frameworks and methods, not placing itself within a single research tradition but rather using a selection of what was available and deemed most useful to realise the project aims.

If we consider the objectives put forth in Article 1, where we aimed to investigate the effect of the ISP on guideline adherence and the effect of guideline adherence on patients and relatives' outcomes, the cluster randomised design was appropriate and a major strength of the study when compared to previous non-randomised efforts (155, 184). We could have compared the ISP to an active or placebo implementation strategy in the control arm, but it would have led to a contamination of the control clusters that would compromise the clinical effectiveness sub-study. Similarly, we could have compared the effectiveness of different family involvement models, using cluster and/or individual randomisation. However, this would complicate the implementation effectiveness sub-study, as clinicians would then purposefully deviate from the national guidelines, making comparisons of fidelity and penetration difficult both within and between arms. Due to limited resources and staff to conduct research and provide clinical training, supervision, and implementation support, it would also not have been feasible to compare the effectiveness of implementation strategies or family interventions in this trial.

The pragmatic approach of the study is also evident from the wide eligibility criteria for clusters. Non-pragmatic study designs with narrow eligibility criteria may produce reliable results that have limited transferability to real-life clinical services and practice, and this trade-off between internal and external validity (94) was an important consideration when designing the IFIP trial. While the inclusion of a spectrum of different clinical units may have strengthened the external validity of the findings, the potential downside was that the variety in service types and patient populations might lead to variable fidelity, penetration, and effect of implementation and clinical interventions. These potential challenges may have been partially offset by the narrower inclusion criteria in the clinical effectiveness sub-study and the limited scope of assessments in the implementation effectiveness sub-study, focusing exclusively on (practices towards) persons with psychotic disorders and their adult relatives. The resulting drop in external validity

may be justified by the fact that the clinical practice guidelines (11) concern the treatment of this patient group specifically, although the same cannot be said for the general recommendations on family involvement in the health and care services (10). An alternative approach could have been to measure the implementation of family involvement practices towards a wider group of patients, while only measuring the effects of these practices on persons with psychotic disorders and their relatives. However, this would affect our possibilities to investigate the relationship between implementation outcomes and clinical outcomes, such as the predictive validity of fidelity.

The reader might have noticed that we list all the fidelity scale outcomes as primary outcomes in Article 1 and the clinicaltrials.gov registration, whereas only the FPE scale is defined as primary outcome in Article 3. This is a consequence of how the trial's sample size was calculated, where only FPE scale data from previous studies were used and the significance level was consistent with a single primary outcome. Enhanced statistical support during the early phases of the project might have prevented this error.

6.1.2. The IFIP intervention and the ISP

The IFIP intervention consisted of implementation interventions that were well-established within mental health services research, and two clinical interventions with highly contrasting evidence status. FPE has been widely used and is well-documented, whereas BFIS was developed as part of the IFIP project. Although similar basic family involvement models have been described (58, 177), to our knowledge none of them have been rigorously tested and evaluated. Furthermore, the BFIS intervention was developed from national recommendations that were not exclusively evidence-based, with their additional grounding in legal regulations, ethical considerations, and stakeholder consensus (10). Thus, the IFIP study involved both the implementation and fidelity assessment of practices that had a more complex rationale than scientific evidence alone. We would argue that this expanded use of implementation and evaluation strategies from previous research on EBP implementation was justified, recognising that many essential practices within mental health services are based on ethical and legal considerations rather than demonstrated clinical effectiveness.

The development of the IFIP intervention was informed by a comprehensive reading of the available evidence, the national guidelines, previous similar studies, stakeholder input, and the identification of barriers and potential facilitators. Although the evidence supporting specific implementation strategies in mental health services was limited, we could have employed the ERIC (140) and EPOC (142) taxonomies to raise our awareness of how comprehensive our strategies were, particularly to assess the feasibility of scaling up. Using an established taxonomy or implementation reporting guideline, such as the Standards for Reporting Implementation Studies (StaRI) Statement (215), could also have improved the reporting of our publications and facilitated the replication of our interventions.

It would have been ideal if the BFIS intervention had been piloted properly before the IFIP trial, as a single intervention or in combination with FPE, to obtain preliminary feasibility, process, and outcome data (129, 204). The BFIS scale could have been piloted simultaneously, with a

more comprehensive testing of psychometric properties. One could also have considered to pilot the whole-ward approach, which was a novel implementation strategy within this field. However, time constraints and limited resources made conducting a full pilot unrealistic and we had to make do with a small-scale assessment of feasibility, appropriateness, and acceptability, as well as the valuable experiences from the BPB project (161). As a result, the IFIP trial might be said to consist of two separate studies that are highly intertwined. On the one hand, we have a rigorous implementation trial of FPE, where both the clinical intervention and the primary outcome measure (FPE fidelity scale) are well-documented and tested. On the other hand, we have an explorative trial of BFIS implementation, where both the intervention and the instrument measuring its delivery are employed and investigated for the first time. The potential benefits of implementing BFIS and FPE together have been described previously in the methods section. A potential disadvantage of this strategy is that it might be difficult to untangle the clinical effects of the various interventions, although we do measure exposure to various forms of family involvement among the participants in the clinical effectiveness sub-study. Even so, this novel combination of basic and advanced family involvement practices highlights the need for qualitative studies of the stakeholders' experiences, exploring what the different elements meant to the participants and how they might interrelate.

6.1.3. General evaluation design and methods

While we were not familiar with the work of Curran et al. (151) when planning the evaluation design, our selection of a hybrid effectiveness-implementation type 2 design was nonetheless an appropriate choice, based on their criteria. There was a strong face validity for the clinical and implementation interventions, both indirect and direct evidence supporting them, minimal risk associated with them, and importantly there was a strong momentum for implementation with administrators seeking to implement the national guidelines as quickly as possible. There were also reasonable expectations of feasibility of the ISP in the relevant clinical units and reasons to gather further data on the effectiveness of the clinical interventions, as they included the novel BFIS intervention and the combination of BFIS and FPE (151). Since both the ISP and the clinical interventions contained a mixture of well-documented and less documented interventions, the hybrid type 2 design appears to have been the best choice to address the relevant knowledge gaps (149). An advantage of conducting a type 2 hybrid study is that one may optimise the implementation conditions, while maintaining pragmatic clinical delivery conditions. This strategy may provide more relevant estimates of effectiveness than conventional effectiveness trials, which sometimes deliberately create "worst case" conditions without external support and attention to implementation factors (151). However, it is important to recognise that optimising the implementation conditions may not be feasible for the services without external support. The hybrid type 2 design can also enable investigations of how clinical outcomes are related to implementation outcomes, such as fidelity (152). The disadvantages are related to the feasibility, cost, complexity, and relatively high risk of such designs. If both clinical and implementation interventions are complex and requires changes to both the organisation and clinical practice, it might be too demanding to handle for the clinical units in question. Hybrid type 2 studies may also require multi-disciplinary research teams with

personnel from different scientific traditions, who may not understand each other well (151). Finally, and perhaps most importantly, if the implementation strategy leads to poor fidelity or penetration it will usually compromise the clinical effectiveness study (152).

Our wide selection of implementation outcomes (146) is a strength of the IFIP study when compared with previous studies, which have mainly focused on fidelity (155, 184). However, the study may also have benefited from including measures to assess the feasibility of both implementation and clinical interventions during the trial, as well as a more clearly formulated theory of how specific elements in the ISP might contribute to sustainability.

The comprehensive process evaluations of the IFIP study covered most of the factors that were recommended by the MRC (134) and provided important insights into the implementation, dynamics, and potential mechanisms of the interventions. A more clearly developed programme theory (129, 133), of how the ISP was supposed to generate change with key uncertainties, could have informed and improved both the preliminary feasibility assessment and the implementation process evaluation. For instance, we did not actively use theories or specific measures of leadership and organisational culture, both of which were targets of our implementation strategies. Since we were implementing a mixture of well-documented and less documented interventions, a more rigorous approach to measure adaptations and important contextual factors would have been useful to better assess the generalisability of our findings (134). The qualitative studies of both implementation and clinical interventions employed an open and pragmatic explorative approach, rather than a theory-driven and focused one. A clear advantage of this strategy is the ability to discover unexpected findings and gain novel insights, but without a theoretical framework or guidance one may also miss important findings during data collection or analysis. Recognising these issues, the qualitative process evaluation studies could probably have struck a better balance between open and focused inquiry, for instance by using implementation science theory more actively. We could also have taken better advantage of our complex experimental mixed methods design, by having one or more joint research questions for the two methodological strands and a plan for conducting convergent analysis with potential meta-inference (207). The general challenges of using mixed methods resemble those of employing hybrid designs, in requiring research teams with multiple skills, as well as additional resources and time (169).

As a consequence of the hybrid study design (151) and limited staffing, there was no separation between the process evaluation team and the outcome evaluation team in the IFIP study. If we consider the evaluation of the ISP (see figure 3), the implementation effectiveness and quantitative process data were collected simultaneously, and fidelity and penetration were part of the quantitative process evaluation of the clinical interventions. The qualitative process evaluations were carried out by the same researchers who measured fidelity, who also contributed to the data collection in the clinical effectiveness sub-study. Advantages of having an integrated team include minimal chances for overlap, balancing and potentially reducing the measurement burden on participants, and a larger potential for integration of process and outcome data (134). Challenges with this approach include not being able to blind outcome assessors and that knowledge of outcomes may bias the interpretations of process data and vice versa, if these analyses are carried out simultaneously. It may also generate potential conflicts

of interest, if the process evaluations uncover findings that may negatively affect the interpretation of the trial results (134). In the IFIP study, the process and outcome evaluations of the ISP were carried out simultaneously and the results from the analysis of fidelity outcomes in Article 3 were known to those conducting the qualitative process evaluation (205), introducing a risk of biased interpretation. The process evaluations of the clinical interventions however, both quantitative and qualitative, were mainly carried out and analysed before any results of the clinical effectiveness sub-study were available.

In the IFIP study, there was also no separation between intervention developers and implementers on the one hand and process and outcome evaluation teams on the other. This arrangement may cause doubt regarding the independence and credibility of evaluators (134). Although the IFIP intervention was developed by the project group, it was based on the national guidelines and contained interventions and strategies that had been developed independently of the project. It is also not unusual for developers to conduct efficacy or effectiveness research on an intervention of their own creation, but it is often remedied by the use of single or double blinding. In pragmatic implementation trials of psychosocial interventions, blinding the recipients of a clinical or implementation intervention is impossible when there is no intervention offered to the control arm. It is also difficult to blind the assessments, because fidelity assessors will be able to deduce the relevant cluster's allocation status. In the IFIP trial, blinding was not an option since implementation support and supervision of the local implementation teams was provided by the same researchers who conducted fidelity assessments. The lack of blinding may have influenced both the performance and the assessment of the clusters. However, as mentioned previously, training and supervision in FPE was provided by TIPS South-East. This means that the risk of experimenter bias was highest when considering the quantitative implementation process evaluation, and probably less critical for the measurement of implementation and clinical effectiveness. The benefit of having fidelity assessors providing implementation support and supervision was that their familiarity with the clinical sites, and in-depth knowledge of their implementation status, made it possible for them to tailor the supervision to local needs.

This brings us to the next important issue, which is that of formative evaluation. While efficacy studies emphasise internal validity and effectiveness studies aim to balance internal and external validity, implementation studies often use formative evaluation that might be said to violate normal standards for internal validity (107), and limit the external validity of implementation effectiveness to studies that employ a similar approach (216). There are at least two important compromises related to the use of formative evaluation. In terms of internal validity, there is a critical balance between generating certain knowledge about the effectiveness of predetermined non-customised interventions, and less certain knowledge about the effectiveness of adapted and more suitable interventions. This tension could potentially be resolved by conducting a pilot with formative evaluation and adaptation, followed by a more stringent and large-scale study of the adapted but fixed intervention. These considerations are also related to the issue of fidelity versus adaptability, which I will address in the discussion of the results. In terms of external validity, there is a second important trade-off between the effectiveness of implementation and the generalisability of implementation effectiveness. Formative evaluation with audit and feedback is a highly effective implementation strategy (143, 144), which makes

it difficult to assess the relative effects of any additional implementation interventions. Thus, combined with the local adaptations resulting from this strategy, its external relevance is limited to the use of similar formative evaluation strategies in similar settings. The appropriate balance between generating local/specific or generalisable implementation knowledge will depend on the overall goal of the study (146). The main objective of the IFIP study was to achieve successful implementation of the national guidelines on family involvement, which warranted the use of formative evaluation through audit and feedback, like previous studies within the field (147, 160, 161).

6.1.4. General methodology of the thesis

Before considering the methods of the thesis' articles, I would like to address some general methodological issues that concern the thesis as a whole. Article 1 will not be discussed below, as the overall methodology of the IFIP study has already been considered in this chapter.

The first question is whether this thesis can be rightly considered a mixed methods study, as indicated by its subtitle. It does contain both quantitative and qualitative studies, but their findings were not mixed during the IFIP study or in its publications. However, as I will attempt to show in the discussion of the results, these studies can be interpreted together in order to form a larger whole. When viewed in isolation, an obvious limitation of this thesis is that it only includes data collected from clinicians. Yet, as described previously, the IFIP study as a whole included both quantitative and qualitative data from all the central stakeholders, and this thesis must be viewed as a piece of that larger puzzle. The partial sample overlap, between Articles 2 and 3 on the one hand and Article 4 on the other, could be seen as both a strength and a potential source of bias. It may be a strength because Article 4 can be seen as an in-depth exploration of the benefits and disadvantages of family involvement, through the eyes of clinicians who generally practiced the models with adequate fidelity. It could also be a potential source of bias, if the excellent fidelity results and positive experiences documented in the qualitative study were based on interviews with the same people, and these came from smaller non-representative groups within each clinical site. Triangulation of sources during fidelity assessments and purposive sampling for the qualitative focus groups were both measures to address this danger, and the resulting partial sample overlap was probably the best compromise. A general reflection concerning all the articles is that we could have involved stakeholder representatives more actively in the analysis and interpretation of our results, although we did consult our advisory board regularly.

6.1.5. Methods of Articles 2 and 3

Articles 2 and 3 should be considered parts of the same implementation sub-study, where the data collection procedures, instruments, and analytical strategies overlapped significantly. Since the general methodological considerations and limitations of the IFIP trial have already been addressed, this section will focus on the instruments, sample, data collection, and analysis of the articles.

As mentioned previously, the BFIS scale should ideally have been piloted before the IFIP trial, together with the BFIS intervention itself. While the BFIS intervention was assessed by the panel groups, advisory board, and participating clinical units and personnel, the scale was developed after this process and did not receive a similar attention. In practice, the baseline measurements became a pilot of the BFIS scale, with the subsequent necessary revisions. Although we were able to adjust the baseline scores after the scale revisions, it is generally not recommended to alter instruments or outcomes after trial commencement. The reason is that if one removes elements that were hard to implement, one risks introducing bias and overestimating the implementation effectiveness. As reported in the methods section however, this was generally not the case in the IFIP trial, where the only BFIS scale element that was 'softened' during revisions was the required frequency of psychoeducative seminars for relatives. Presently, the BFIS-S subscale measures fidelity to both clinical and implementation interventions and the BFIS-P subscale covers both clinical and procedural measures, which might be confusing. There is also a potential for some BFIS scale items to be more clearly defined, and to consider splitting items and sub-items that combine structure with process and/or penetration (217), in any post-trial revisions of the scale. Developing a fidelity review manual would also have helped to standardise the BFIS scale measurements, but was difficult without first conducting a formal pilot (148). A final challenge with the scale is that it does not measure the penetration of phone calls, which is often the main mode of communication between clinicians and relatives. The FPE fidelity scale (primary outcome) and the GOI scale were not altered at any point during the IFIP study.

The convenience sampling of regular clinicians for fidelity assessment interviews was the most feasible choice for the clinical sites, with local coordinators or leaders selecting personnel that were working on the relevant day and not too busy with other tasks. Although there is a risk associated with recruitment through local leaders or personnel, we did not get the impression that the selected participants misrepresented the local practice or that a more random selection of clinicians would provide us with a different picture. Since we conducted a large multi-site study with limited staffing, it was not feasible for us to systematically observe family involvement practices or interview patients and relatives, both of which could have strengthen the validity of process-related item measurements. We did have intentions, and REC approval, to conduct chart reviews of randomly selected patient records. However, the introduction of the GDPR legislation in Norway put an effective stop to these plans, as the newly appointed data protection officers in each health trust required us to follow highly varying and labor-intensive procedures that were not feasible for the project. This was unfortunate, since chart reviews would have strengthened the validity of our measurements, particularly of the BFIS penetration rate items. As a result, there was a risk of 'self-report' or 'social desirability' bias, which was probably most critical for non-structural items that were more open to subjective interpretation (217). While not optimal, clinicians' self-report of content and structure of family interventions may be less prone to bias than previously thought (218). We should also note that neither the BPB project (161) nor Kealy et al. (184) used chart reviews, observations, or interviews with patients and relatives to score FPE fidelity. As the penetration rate of FPE was based on administrative data, the measurements were not subject to a similar risk of bias. However, these rates could have been more differentiated to assess the number of sessions or specific milestones

(184) provided to the target group. When calculating the penetration rate, we assumed that all patients with psychotic disorders were eligible for FPE, which is probably an overestimation. Furthermore, we only included the patients currently receiving treatment at the clinical site in question. Thus, the clusters were not credited for discharged patients that had received FPE, and the results may therefore not reflect all their effort. Finally, we could have systematically monitored and reported the number and percentage of clinicians who attended various training and supervision activities, although these domains were partly covered by the BFIS and GOI scales. It is difficult to assess the impact on our fidelity assessments, from having to perform measurements through a digital platform during parts of the coronavirus pandemic. As the measurements were mainly interview-based, and we had relevant written material sent to us from the units, the effects were probably not that large and the possible impact would have been similar in both arms at 24 months.

The assessment and analysis of psychometric properties for the BFIS scale could have been more comprehensive. We could have calculated a measure of internal consistency, such as Cronbach's alpha, which might have made us consider rearranging the subscales. However, fidelity scales often have poor internal consistency, because the EBPs in question consist of a spectrum of interventions with uncorrelated levels of implementation (148). Assessor-reported feasibility and acceptability was considered after the baseline measurements, but could have been measured and reported systematically according to pre-specified criteria. The investigations of IRR for all scales were carried out and analysed in the same manner as in previous studies using the FPE and GOI scales (155, 156, 182, 184), without considering test-retest reliability (148). Discriminant validity was assessed first by investigating the correlation between the units' FPE status and the BFIS scale scores in Article 2, and later by comparing the scores of experimental and control clusters in Article 3. The repeated measurements during the implementation period, reported in Article 3, also provided the opportunity to assess whether the BFIS scale was sensitive to change. Predictive validity can first be considered when the results of the clinical effectiveness sub-study are available.

We experimented with several models for analysing fidelity outcomes, including LMMs with fixed effects and simple linear regression models that only included the measurements at baseline and 24 months. However, the challenge was to estimate models that could handle dissimilar numbers of repeated measurements between the arms. This challenge was addressed by using dummy variables in the final model, accounting for a potentially non-linear trend in the experimental arm. The post hoc analyses were not adjusted for multiple testing and the results, including p-values and effect sizes, are explorative and must be interpreted with caution.

6.1.6. Methods of Article 4

The explorative qualitative design of Article 4, while nested in the larger IFIP study, presents us with different methodological challenges and questions than those of the other articles in this thesis. Article 4 constitutes a part of the qualitative process evaluation of the clinical interventions, investigating how these were experienced by the clinicians who practiced them. However, the findings also provide important insights that are relevant to understand the

implementation process, and how it might have been affected by the clinicians' perceptions of the clinical interventions. The research question and focus of this sub-study was the result of an interactive process (219), building upon the previous qualitative studies of the IFIP project, the study's goals and conceptual framework, and relevant scientific literature. While the study explored the processes and potential effects of family involvement, the qualitative methodology was not suitable to assess causality, but may generate hypotheses for quantitative research.

Using a purposeful sampling strategy was appropriate to ensure that we interviewed clinicians who had practiced family involvement, while reaching participants with various professional backgrounds, clinical roles, and commitment to the models implemented. It was also essential for the study to conduct interviews with clinicians in all the experimental sites. Thus, we sought to recruit participants that were representative of the phenomenon under study, and at the same time to account for some of the variety within that group (220). The sampling strategy had to take into consideration that both the ISP and the clinical interventions were to be explored through the same data material, as part of the mixed methods process evaluations. By conducting focus groups with both implementation teams and ordinary clinicians, we combined criterion sampling with a maximum variation sampling, which is a frequently used and recommended strategy within mixed methods implementation research (221). Although we specifically asked the local leaders to recruit at least one participant who was indifferent to or skeptical of family involvement, there is a risk that 'dissenters' were not asked or that they refused to participate. It is also possible that interviewing clinicians in the control arm or in the CMHCs that refused to participate would have provided us with additional perspectives. However, these clinicians would generally lack experience with the clinical interventions being studied.

By being relatively broad, open, and balanced, the general topics listed in the interview guides were intended to elicit clinicians' experiences, without leading them too much in any predetermined direction. As described previously in this chapter, the data collection might have benefited from using implementation science theory more actively to assess important determinants and contextual factors through more focused questions. The interview guides could have been revised between focus groups, but our experiences from the first groups nonetheless influenced how we later phrased and prioritised the various topics. While the focus groups with implementation teams followed up on a previous round of such groups, we did not conduct follow-up groups with the ordinary clinicians. The major disadvantage of not conducting follow-up groups was that we were unable to ask the clinicians about important topics that had surfaced in later groups (222). The focus groups could have been supplemented with individual interviews, to compensate for some of the disadvantages of the focus group format. For instance, there is a risk that clinicians did not speak their mind freely in the presence of colleagues and researchers, because they considered their opinions controversial or unpopular, or that their opinions mattered less because of professional hierarchies or other factors. Contact and interactions over time resulted in extensive knowledge of and familiarity with the clinical sites and their employees. While this contact was related to the ongoing implementation support and data collection and did not qualify as participant observation (222), it provided us with the opportunity for 'informal data gathering' (220). However, we could have made systematic field notes to include as data material for this qualitative study. Additional

data material, such as written communication and other document or text sources, would probably have been less useful to explore clinicians' perceptions of the clinical interventions.

I chose to employ Braun and Clarke's method for reflexive thematic analysis, since it is relatively straightforward and lends itself to various purposes and paradigms (209, 210). A realist inductive approach to identify semantic themes was an appropriate choice, given the character of the research question and of the IFIP study in general. A phenomenological approach (223) would have focused too much on clinicians' individual experiences, and not been appropriate to identify general patterns of experience and meaning across our large sample of focus groups. A constructivist approach, such as discourse analysis (224), would have been appropriate to identify general patterns and meanings, but mainly if we were concerned with how structural and sociocultural factors affected the clinicians' experiences and expressions. I could have used grounded theory (225), which shares several traits with the chosen analytical approach, but it is a more comprehensive and labor-intensive method. Furthermore, its relative advantage of larger theory-development was not required to answer the research question. Due to time constraints, we did not transcribe the focus groups ourselves, something many qualitative researchers recommend as being the first step of qualitative analysis (209, 222). However, we did conduct the focus groups ourselves and used a significant amount of time on the immersion phase of data analysis (209). In the article, we mainly interpreted clinicians' experiences and perceptions of the processes and dynamics of the clinical interventions, to avoid overlap with the qualitative implementation process evaluation that was based on the same data (205).

The concept of validity has been controversial within qualitative research, where some scholars have seen it as an import of positivist standards and assumptions of an objective truth or reality (226). Alternative concepts that are frequently used include the terms 'credibility' and 'trustworthiness', describing whether potential validity threats have been addressed to make the interpretations and conclusions of a given study appear sound (227). The terms correspond roughly to the concept of internal validity in quantitative studies. There are several strategies to strengthen the trustworthiness of a qualitative study. In this study, we used data triangulation (226) by interviewing different categories of clinicians and by comparing the preliminary results with those of a similar analysis of patients' experiences. To counteract researcher bias, the preliminary findings and themes were discussed thoroughly with the other co-authors to look for possible alternative explanations or interpretations. Since we were employing reflexive thematic analysis, we did not use coding reliability or similar measures (210). Regardless of the interdisciplinary nature of our research group, we recognise that we may share many of the same biases and preconceptions, and the preliminary results were therefore also discussed with our advisory board, with useful input on both identified and potential themes. A few anonymised extracts from the transcripts of interviews with patients, relatives, and clinicians were presented to the personnel during supervision and training days, to inspire them and to see how the findings resonated with their experiences. Unfortunately, we did not have time to perform respondent validation (227) on the final analysis and interpretation, which would have increased the trustworthiness of the study. Reactivity, the influence that a researcher has on the participants in a qualitative study (226), was a potentially critical source of bias in these focus groups, where the researchers had an avowedly non-neutral position towards the clinical

interventions. We attempted to address these concerns through a reflexive process (see below) during data collection and analysis, where we consistently sought to elicit and identify critical perspectives on the clinical interventions.

Transparency is another important trait of good qualitative research (222). In this study, we strived to report our methodological and analytical approach, as well as the ontological and epistemological assumptions (see below) underpinning it. Using the Standards for Reporting Qualitative Research (SRQR) (228) also enhanced the transparency of the study.

Even if representativeness in a quantitative and statistical sense cannot be achieved in a qualitative study, the concept of 'transferability' is nonetheless important and corresponds to the concept of external validity in quantitative studies (229). The issue in qualitative studies however, is not to assess whether findings are generalisable, but to evaluate how relevant they are to other persons and contexts (222). In this regard, the randomised design of the IFIP trial is a major strength of this qualitative study, which explores the experiences and perceptions of a wide range of clinicians, whose clinical units were randomly selected to receive training and implementation support. This suggests that our findings may be relevant to other clinicians who work in similar settings and with similar patient groups.

6.1.7. Ontological and epistemological positions

The researcher's or a scientific community's fundamental assumptions concerning 'ontology', the nature of reality and existence, and 'epistemology', the nature of knowledge and its creation, have wide implications for how the aims, methods, and results of a research project are created and understood. In mixed methods research, the issue of philosophical positions has been particularly contentious. A central question has been whether the largely constructivist paradigms of qualitative research traditions can be mixed with the mainly positivist assumptions of quantitative research communities, and how (230). Several mixed methods researchers and theorists have found this debate unproductive, and come to adopt 'pragmatism' as a practical philosophical approach instead. The latter approach emphasises how the aim or research question should determine the choice of methods, rather than one's philosophical assumptions or particular scientific tradition (230). If we consider the IFIP study as a whole, it can generally be described as falling within this pragmatic tradition. However, the pragmatic approach deliberately fails to articulate an ontological and epistemological position, by accepting reality as both singular and multiple and knowledge as both subjective and objective, depending on the research question. Another perspective, which is increasingly employed within mixed methods research and describes my own philosophical position quite well, is that of 'critical realism'. The critical realist position combines a realist ontology, assuming a real world that exists independently of our perceptions and theories, with a constructivist epistemology, acknowledging that all forms of knowledge and understanding to some degree reflect the researcher's subjective perspective and standpoint, making pure objective knowledge unattainable (231). These positions can be recognised in Article 4, where we assume that the clinical interventions' effects on the stakeholders is a real-world phenomenon, and at the same time that exploring multiple perspectives on the processes of that phenomenon is a valid form

of knowledge-generation. The qualitative results are intersubjective and co-created interpretations of those processes, rather than objective truths extracted by the researcher (232). Although the effectiveness sub-studies of the IFIP trial employed structured and instrument-based data collection to generate quantitative data, these were also the result of intersubjective processes that involved multiple perspectives.

6.1.8. Reflexivity

The realisation that all knowledge-generation will be influenced by the researcher's background, perspectives, and position, demonstrates the need for a continuous reflexive process. It is important to account for the effects of the positioned researcher, by systematically identifying the researcher's preconceptions and the way these may impact the research process (229). As a medical doctor, I approached this project with certain ideas about the nature of illness and treatment that have been challenged by discovering how family involvement is one of the best-documented treatments for persons with psychotic disorders. At the same time, my training in evidence-based medicine perhaps made it easier for me to accept this fact when faced with the evidence, and even more shocked by the lack of implementation in the services. Being a physician, but not a mental health professional, may have been a strength in the sense that I had some understanding of the clinicians' situation and perspective, while being enough of an outsider to ask 'stupid' questions and to avoid taking things for granted. As a person who is trained in both social anthropology and medicine, my pre-understanding and competence was in many ways appropriate to understand and value the different methods used in our mixed methods project. Unlike some of my colleagues, I have no personal experience with serious mental illness in a family member. This might allow me to assume a more dispassionate and neutral position, but it can also cause me to miss out on certain nuances or meanings of participants' expressions. Our position as non-neutral and embedded researchers and its potential effects on data collection, analysis, and interpretation has already been discussed and will not be elaborated further here.

6.1.9. Ethical considerations

The interventions and design of the IFIP study merit some ethical considerations. In the Helsinki Declaration (211), particular emphasis is placed on weighing benefits against burdens when deciding whether to conduct a research project. Importantly, this involves not only assessing benefits to patients with a similar condition, but also to the research subjects themselves (211). This compromise between utilitarian and deontological considerations is evident throughout the declaration, where research is portrayed as necessary for medical progress, while this objective can never go past the rights, interests, and health of the research subjects (211). If we consider the IFIP study in general, we have systematically altered the health services while conducting research on patients, relatives, and health personnel. As such, we must consider the potential benefits and disadvantages for the various study participants and stakeholder groups, of both our interventions and our research.

Starting with the clinical interventions, we have reviewed evidence in the background section that would highly suggest that patients and relatives stood to benefit from them. The potential harm of family involvement for these groups was minimal, when clinicians conducted proper eligibility assessments. For the clinicians, the burden of increased responsibilities should have been alleviated by allocation of sufficient time and resources, as well as the potential increase in work satisfaction from offering high-quality and evidence-based services. At a clinical level, ethical challenges of family involvement include the danger of placing extra responsibility on family members for the patients care and follow-up, while they have their own needs to attend to. It might also be challenging to teach the family how to handle the illness better without blaming them (46). Another challenge is how to handle the duty of confidentiality and conduct family involvement without compromising the therapeutic alliance between patient and clinician (206). At a societal level, there is also a balance between using informal care resources to improve treatment and relieve the health services, and the risk of productivity loss among relatives from assuming too much responsibility. The IFIP study has paid particular attention to these ethical dilemmas, and we consider none of them to be valid arguments against family involvement in general. We are aware that the FPE model is grounded in a specific biopsychosocial understanding of psychiatric illness and that some critics would question the value of the model and its documented outcomes, such as increased adherence with medication. Nonetheless, we felt morally obligated to use the best evidence available, and the clinical interventions only complemented and reinforced the existing treatment strategies within the services.

Concerning the ISP, we generally considered that the burden of implementation activities on clinical sites and personnel would be outweighed by the benefits of systematic family involvement for all stakeholders, particularly in a long-term perspective. The whole-ward approach however, required a heightened awareness of potential ethical dilemmas (46). When recommending that all patients and relatives should receive the BFIS intervention, we risked introducing a form of informal coercion that could violate the principle of respect for autonomy (233). It was therefore vital that patients understood that they had a real choice and could refuse to consent to family involvement and/or participation in the IFIP study, without any consequences to their treatment.

If we consider potential ethical challenges of our research activities, the cluster randomised design required more participants in the clinical effectiveness sub-study than a regular randomised controlled trial (202), and the Helsinki declaration states that it is unethical to subject people unnecessarily to the risks of research (211). As such, it was important that the study design was justified by the potential knowledge generated through it, something which has been accounted for in the previous parts of this thesis. Another ethical challenge related to the study design was that consent to randomisation was sought at the cluster level, meaning that patients and relatives did not have the opportunity to consent to randomisation between interventions, and were only able to refuse to participate in the intervention and/or the study (202). We should therefore emphasise that we were not limiting or negatively affecting the clinical practice in the control clusters, whereas we contributed positively to the clinical practice in the experimental clusters. It was also possible for patients and relatives in the experimental

arm to consent to family involvement without participating in the clinical effectiveness sub-study, and for clinicians in the control arm to offer family involvement to study participants. However, the cluster randomised design might be said to have delayed the implementation of family involvement in the control arm, thereby also delaying its potential benefits for the patients, relatives, and clinicians in these sites. Due to limited resources to teach and supervise FPE, this delay was more theoretical than actual, and it would be more accurate to say that we redistributed these resources in accordance with our study design. In addition, we offered the control clusters teaching and supervision after the trial was completed.

We considered that the potential value of the knowledge produced, both to the stakeholders at the clinical sites and the stakeholder groups in general, would justify the use of resources and the potential burdens on the participants in our study. However, the need to divert clinicians' time and attention away from patient-oriented activities must always be considered carefully, and we have strived continuously to minimise this burden whenever possible. Since this thesis did not involve data collection from patients and relatives, I will not discuss the ethical implications of the eligibility criteria and informed consent procedures of the clinical effectiveness sub-study and the qualitative studies on patients and relatives' experiences. However, it should be mentioned that persons with psychotic disorders can be considered a vulnerable group (234). According to the Helsinki declaration, this means that there is an increased potential for harm and that research within this group must be responsive to their health needs and priorities, that carrying out the research within a non-vulnerable group is not possible, and that the group will stand to benefit from the knowledge, practices, or interventions that the research generates (211). These considerations have been central to the planning of the IFIP study.

6.2. Discussion of the results

In this chapter, I will discuss the findings of the articles in this thesis and compare these to the results of previous relevant studies. The articles will first be considered separately, followed by an integrative discussion and interpretation guided by the CFIR framework's innovation/intervention characteristics domain (138, 139) and Proctor et al.'s classification of implementation outcomes (146). While not being a part of this thesis, I will also include and discuss selected findings from the other qualitative articles of the IFIP study (205, 206, 235), since omitting these results would result in an artificially limited discussion.

6.2.1. Article 2

Article 2 documented the overall poor level of implementation of the national guidelines among our participating clinical sites at baseline, where the lack of procedures and systematic training was accompanied by random and inadequate family involvement. These findings resonate with the results of previous studies that have either documented a low implementation of family interventions in mental health care (1-4, 98, 99), or explored relatives' generally poor experiences with mental health services (100-106). The findings are also corroborated by the later reports, which in various ways have assessed the level of family involvement in Norwegian general or mental health care (121, 126-128). Another important insight of this article was how varied the services for this patient group were in general, and not just with regards to family involvement. The established procedures and personnel responsible for following up children as next of kin, 10 years after the relevant legislation (119) was passed, might indicate that legal mandates are more influential than guidelines or that time is required for the services to implement such practices. Health professionals' education in Norway have generally not focused much on family involvement practices. Thus, given the lack of systematic and regular training within the health services, these baseline results are unfortunately not surprising.

Despite the lack of piloting and subsequent need for revisions, the BFIS scale demonstrated its usefulness, relevance, and applicability during the baseline measurements. To our knowledge, this was the first time that such a wide and comprehensive spectrum of family involvement practices for persons with psychotic disorders were systematically assessed in CMHCs. The findings should therefore be of value and interest to both researchers and central stakeholders. Preliminary measures of IRR were generally good and the lack of significant correlation between the BFIS scores and the units' FPE status could be an indication of discriminant validity, although these findings should be interpreted with caution. A possible explanation for the borderline significant association, between item 13 and the units' FPE status, could be that the units who offered FPE would document these groups in the discharge reports.

6.2.2. Article 3

Article 3 described how the ISP had a substantial effect on the family involvement practices in experimental clusters, increasing their level of adherence to the national guidelines significantly when compared to the control arm.

As the first instrument of its kind, with no piloting and evaluating a novel intervention with a moderate to high risk of bias, the significant changes in the BFIS scale scores should be interpreted with caution as a measure of implementation effectiveness. However, the mean scores on the BFIS scale and its two subscales all reached 4.0 at 24 months in the experimental arm, suggesting that basic family involvement practices were improved in terms of structure, content, and penetration. The results may also indicate that a score of 4.0 could be an appropriate benchmark value (148) for the scale. Fidelity to the structural and content-related elements of the BFIS-S subscale rose sharply during the first six months of the implementation period, whereas the BFIS-P penetration subscale scores increased progressively throughout the trial. This might reflect that there is a certain delay before organisational and procedural changes reach patients and relatives (147, 155, 157).

To our knowledge, this is the first time that a cluster randomised trial has achieved a significant increase in fidelity to the FPE model in the experimental arm, with service-wide adequate fidelity for persons with psychotic disorders in CMHCs. All the experimental clusters offered FPE at 24 months, where each site scored ≥ 4 and the mean score was 4.48, which is very good compared to previous studies. Non-randomised implementation studies have been able to achieve moderate (184) to adequate (155, 183) fidelity, while the cluster randomised BPB study reported moderate fidelity after 18 months of implementation support, and no significant differences between experimental and control conditions (161). However, if one excludes the drop-out sites of BPB from the analysis, like the NEBP project did (155), the final results of these two studies are quite similar, with adequate mean fidelity scores after 18-24 months of implementation support (182). Still, because of the drop-out rates, only 39-50 % of sites in the latter two studies and Kealey et al.'s study reached adequate fidelity (155, 161, 184). Similar to those three studies, the FPE fidelity scores in the IFIP trial followed a gradual slope, with the highest increases during the first year of the implementation period.

Another measure of FPE implementation success is the number of sites initiating or completing at least one group, where previous studies have reported 29-100 % of sites initiating (179, 183, 184, 186) and 65% of sites completing (184) a group. In the IFIP study we did not register these numbers, but from the FPE fidelity scores we can conclude that 100 % of experimental sites both initiated FPE groups and reached the problem-solving sessions (the final stage) with at least one group. In contrast to the IFIP study, the studies mentioned in this paragraph implemented multifamily groups, which are more difficult to initiate and perhaps also more difficult to complete than single-family groups.

As described previously, many cross-sectional and audit studies have reported a poor penetration of family interventions, but few implementation studies have included the penetration rate of family interventions as an implementation outcome. Gorrell et al. (181) reported that 47.1 % had received FPE, a non-significant increase from 40.4 % after the implementation of guidelines for early psychosis treatment in Australia. Van Duin et al. (160) reported that 10 % of 30 mental healthcare teams had provided family interventions according to protocol to over 70 % of their patients, a rise from 0 % after a major implementation effort in the Netherlands. In the IFIP trial, the penetration rate of FPE rose significantly from 6.76 % to 12.84 % in the experimental arm during the implementation period. This relatively modest

increase could be due to several factors. Unlike Gorell et al. (181), the IFIP study targeted a wide spectrum of CMHC units and not just early intervention services, in which the majority of clients would be eligible for family interventions. We nonetheless assumed that all patients with psychotic disorders were eligible for FPE when calculating the penetration rate, which probably was an overestimation, even for the early intervention services (236). Other factors that may have affected the penetration rate include capacity issues within the services, the relatively short observation time, and the coronavirus pandemic. The latter generated lockdowns and restrictions from two months before the 18 months fidelity assessments and throughout the trial, resulting in a dip in the FPE penetration rate at 18 and 24 months. In contrast, the BFIS-P mean score at 24 months suggested that these BFIS items had an average penetration rate of 60-80%, which was far better than the FPE penetration rate. This might be due to the fact that BFIS practices are less time-consuming and easier to implement than FPE, but probably also because we advocated that all patients and relatives should be offered BFIS, which resulted in BFIS being integrated in the standard procedures of many experimental units (205). Similar to the findings of the SINTEF evaluation from 2021 (126), we have no indication that the clinical care pathways for mental health and addiction resulted in improved family involvement practices in either arm. However, the lack of data points at 12 and 18 months in the control arm makes it difficult to evaluate the impact of external influences, such as the clinical care pathways and the coronavirus pandemic.

The GOI scale results in the experimental arm were generally good, with an overall mean score of 4.01 and 71 % of sites reaching a mean score ≥ 4 at 24 months. Previous studies have employed the GOI scale when implementing IMR and reported mean scores of 2.99-4.10, with 18-50 % of sites reaching a score of 4 after 12-24 months of implementation support (156, 237, 238). Together with items 1, 2, and 14 in the BFIS scale, the quality improvement and individualisation subscales of the GOI constitute the quantitative process evaluation of the ISP. However, I must emphasise that the BFIS items 1 ‘Training and supervision’ and 2 ‘Family coordinator’ were also measures of adherence to the national guidelines. The generally high scores indicate good adherence with implementation interventions such as the family coordinator and the implementation team; receiving training and supervision; establishing procedures; employing tools, and using fidelity scores systematically to improve the services. As such, the adequate fidelity to the implementation interventions would suggest that these were important in generating adequate fidelity to the clinical interventions. Since we were unable to distinguish between the effects of the various implementation interventions, the qualitative implementation process evaluation (205) was important to explore how these interventions may have acted as facilitators for implementation. Clinicians generally reported that their local family coordinator helped to organise the provision of BFIS and FPE within the unit, while also being a source of motivation, competence, supervision, and increased awareness. Their experiences with the implementation teams were mixed, where some worked well and others did not, often as a result of varying leadership commitment. Ensuring leadership commitment was perceived as a critical facilitator for implementation, where leaders had to explicitly value and prioritise family involvement through allocating sufficient resources. Standardisation through the establishment of procedures and the use of the conversation guide was reported to promote normalisation and integration of family involvement within the units’

regular clinical practice. The external implementation support, including clinical training, supervision, systematic monitoring, and tailored feedback was perceived as an essential facilitator, but also led some clinicians to question the sustainability of these practices after the project's completion (205). A mixed methods process evaluation of the NEBP project similarly emphasised the importance of leadership commitment, as well as the value of audit and feedback through fidelity assessments, when adopted and used systematically by the local leaders and clinicians (147).

While we adopted many of the implementation interventions described above from previous fidelity-based studies of FPE implementation (155, 161, 184), some additional implementation strategies were employed during the IFIP trial. By implementing BFIS and FPE simultaneously, we may have enhanced the uptake of both by the clinical sites. Increased contact with families through systematic BFIS practices may have lowered the threshold for initiating FPE (58, 205). The whole-ward approach was also perceived as important by the clinicians in the IFIP study, where unit-wide training and supervision fostered a shared understanding, increased awareness, and family-friendly culture, with the majority of clinicians seeing family involvement as an important part of their clinical work (205). A particular focus on the engagement phase, and training in how to handle the duty of confidentiality, helped clinicians to overcome and reinterpret central barriers to initiating family involvement (206). This also shows the utility of using formative evaluation to identify and address barriers in real time during an implementation project. By focusing on family involvement practices, rather than implementing a spectrum of EBPs (155, 160, 161), it was perhaps easier for us to detect and address specific barriers to family involvement, in addition to the general obstacles to EBP implementation, at both clinical and organisational levels.

6.2.3. Article 4

Article 4 was a nested qualitative exploration of clinicians' perceptions of family involvement in the treatment of persons with psychotic disorders. The analysis and interpretation of the data material was mainly concerned with the clinical significance of the interventions, regarding benefits and potential disadvantages for the various stakeholders. As such, the publication must be viewed as part of the qualitative process evaluation of the clinical interventions, together with the qualitative explorations of patients and relatives' experiences with family involvement. However, the results may also be interpreted to shed light on potential determinants of implementation, related to clinicians' perceptions of the interventions. The focus of this section will be on the clinical significance of the results, whereas the next section will interpret the results within an implementation context. The 'benefits' theme 1 and the 'disadvantages' theme 1 will both be discussed in the next section, as they mainly concern the usability, appropriateness, and acceptability of FPE. Since the results of the clinical effectiveness sub-study and the qualitative exploration of relatives' experiences have not yet been published, this section will only compare the results of Article 4 to the findings of previous relevant studies and the results of the IFIP study's qualitative exploration of patients' experiences (235).

The findings of Article 4 contributed to the understanding of the dynamics and processes of family involvement in mental health care, by investigating a combination of basic family involvement practices and the advanced family intervention FPE, for persons with psychotic disorders. It described how clinicians, whose units practiced family involvement with high fidelity, perceived the benefits of these practices, but also how they experienced potential challenges and disadvantages. Previous qualitative investigations of clinicians' experiences with FPE and similar family interventions have predominantly focused on challenges and barriers (84, 85, 239). The 'bird's-eye perspective' of clinicians was a strength of the data, as they were in a unique position to assess the benefits and potential disadvantages for patients, relatives, and themselves. However, clinicians also had their blind spots, and the results should therefore be corroborated and complemented by qualitative studies on relatives and patients' experiences with similar interventions.

Overall, the findings of Article 4 added to the existing qualitative literature by showing how the benefits discussed in previous studies applied to all the three stakeholders, and further how clinicians facilitated these beneficial processes through establishing trust and spaces for productive and supportive communication. The three main themes that were identified were 'reducing conflict and stress', 'a triadic understanding', and 'being on the same team'. If we begin with the theme of 'reducing conflict and stress', the few studies that have explored patients and relatives' experiences with FPE emphasise how improved communication patterns and a reframing of relatives' understanding may reduce conflict and stress within the family (79-81). In Article 4, we identified similar processes, which support the theory that FPE leads to a reduction in EE within the family, through a reframing of relatives' understanding that leads to reduced relapse rates (78). Our findings further indicate that relatives' understanding of negative symptoms was particularly important, and that increased understanding among relatives may improve the monitoring and follow-up of the patient. The results also provide a more comprehensive picture of these processes than previous studies. Article 4 described how increased understanding led to reduced conflict and stress, but also how reduced conflict and stress was an important foundation for increased understanding. Conflict was reduced, not just between the patient and the relatives, but also between the health services and the relatives, and stress was reduced for all three stakeholders. Similarly, the qualitative study on patients' experiences showed that the potential reduction in stress among patients, resulting from improved cooperation between their relatives and the health services, probably has been underappreciated (235).

Concerning the theme 'a triadic understanding', clinicians described how the process of gaining increased understanding involved all three stakeholders. The establishment of a shared understanding of the illness led to a better understanding of the patients among their relatives. This was also recognised by the patients participating in the other qualitative study, where they emphasised how increased knowledge and understanding among their relatives enabled them to provide better support (235). Through family involvement, the clinicians also understood the patient and the relatives better, whereas the relatives understood the clinicians and the health services better. Although it was not emphasised by the clinicians, the qualitative study on patient's experiences showed how the latter also understood their relatives better (235). Increased mutual understanding within the family, as well as increased family cohesion and

unity, has been described in previous qualitative studies of family interventions (82, 83). In Article 4 we described a 'triadic understanding', which was the combination of an increased mutual understanding and acknowledgement and a shared understanding, connected through a mutually reinforcing process.

In addition to reducing conflict and stress and gaining a triadic understanding, the clinicians described the feeling of 'being on the same team'. They reported how reduced feelings of loneliness and an increased sense of belonging and inclusion seemed important to both relatives and patients participating in single-family FPE, similar to the findings of previous qualitative studies on multifamily interventions (79, 82, 240). While qualitative studies on general family involvement in mental health care have described a 'team feeling' between relatives and clinicians (41, 88, 200, 241, 242), we reported how clinicians in our study considered that all the three stakeholders were on 'the same team'.

In Article 4, important sub-themes were presented in connection with the main theme that they were mostly associated with. However, as can be seen in figure 1 of the article, all sub-themes were connected to two main themes, where 'reducing conflict and stress' was one of them. This demonstrates the challenges of presenting findings that are highly interconnected. All the sub-themes concerned how clinicians facilitated the family involvement process, in order to achieve the benefits described in the main themes, together with the patients and their families. Creating a space for relatives' experiences, emotions, and needs was important to remedy any conflict between the relatives and the health services, reduce stress for all the stakeholders, and increase clinicians' understanding of the relatives' situation and perspective. The patients who participated in the other qualitative study valued how relatives were provided a space for themselves, although some of them found it uncomfortable to wait for the joint sessions to start while their relatives were attending the alliance sessions (235). Establishing an open line of communication as early as possible was essential for clinicians to provide continuous support to relatives and high-quality follow-up of the patient, to enable information exchange, and to empower relatives to act as a safety net. Just having the possibility to contact the services appeared to reduce the relatives' stress level substantially, while the study on patients' experiences suggested that it also reduced the stress among patients, who valued having their relatives as a safety net (235). Previous qualitative studies of family involvement in mental health care have also described the value of offering relatives a space by themselves (45, 86, 88, 200, 243), as well as the importance of having an open line of communication (41, 88-90, 200, 242).

Finally, clinicians reported how they created a space for patients and relatives to discuss sensitive topics, characterised by trust, openness, and support. It was described as an important foundation for achieving a triadic understanding, while also reducing conflict and stress. Both the results of Article 4 and the findings of the study on patient's experiences emphasised how clinicians created such a space, where they also explained to the relatives how the illness affected the patient, on the patient's request. Previous qualitative studies of highly varying family involvement models have described a similar process, where a space to discuss sensitive topics may lead to increased understanding and acknowledgement (41, 79, 80, 82, 83, 87, 201, 243-245). Grácio et al. (78) suggested that this may reflect how the common therapeutic factors

– therapeutic alliance, support, and the opportunity to share – may contribute substantially to the effectiveness of family interventions.

The reporting of perceived disadvantages or challenges of family involvement should be considered a strength of this article, demonstrating how we have sought out disconfirming experiences and critical voices systematically to provide a comprehensive picture of clinicians' perceptions. Barriers to implementation at the organisational and clinical levels had already been explored as part of the qualitative implementation process evaluation (205, 206), and the relevant findings were discussed together with the results of Article 3. Article 4 on the other hand, considered potential challenges that clinicians experienced when providing the clinical interventions. The lower frequency and larger variety of reported challenges, when compared to benefits, was prominent. Some challenges were inevitable, such as being involved more than usual and handling the risk of becoming the relative's therapist, where the latter has been recognised in previous studies (241, 246). By systematically involving family members, clinicians would also encounter relatives that might constitute a potentially negative influence on the patient, but in most cases they considered that family involvement was useful and required nonetheless.

6.2.4. Perceived intervention characteristics, implementation determinants and outcomes

In this subchapter, I will attempt to integrate and interpret some of the findings of the thesis, guided by the CFIR framework's intervention/innovation characteristics domain (138, 139) and Proctor et al.'s classification of implementation outcomes (146). The central aim is to provide a better understanding of how clinicians' perceptions of the clinical interventions might have affected the implementation results. It is worth noting that the original CFIR framework defined most of the constructs of domain I as the relevant stakeholders' perceptions of them (138), whereas the updated framework does not specify how the constructs should be assessed (139). While the other CFIR domains may contain relevant determinants for the implementation outcomes, the innovation characteristics domain is probably the most appropriate to interpret the qualitative findings of this thesis. Proctor et al. (146) advocated for research to study the interrelationships among implementation outcomes. Although I will not test such relationships statistically, I will explore the relationships between fidelity and penetration on the one hand and perceived acceptability, appropriateness, feasibility, and sustainability on the other. This division is consistent with figure 3 in the methods section of this thesis, where I regarded fidelity to and penetration of the clinical interventions as measures of implementation effectiveness, whereas acceptability, appropriateness, and feasibility were categorised as process outcomes.

If we begin with construct A of CFIR domain I, 'innovation source' (139), the clinicians in Article 4 explicitly recognised and valued that the clinical interventions operationalised the national guidelines. In the qualitative implementation process evaluation, they also considered that the clinical training and supervision was essential, and regarded both TIPS South-East and the University of Oslo as credible sources of external support (205). Innovation source is closely connected to construct B, 'innovation evidence base' (139). The clinicians in Article 4 were conscious that FPE was an EBP, and therefore considered that learning and practicing family

involvement was part of their professional development. Concerning construct C, 'innovation relative advantage' (139), we did ask the clinicians specifically whether we should have included or prioritised other interventions or measures (appendix 4), but none of them compared BFIS and FPE to other interventions in terms of relative advantage. In Article 4 however, they compared practicing systematic family involvement to not doing so, and found that the benefits of family involvement clearly outweighed the disadvantages. Thus, they saw the relative advantage of implementing the clinical interventions, rather than continuing their current practice. If we consider construct F, 'innovation complexity' (139), the qualitative implementation process evaluation showed that clinicians perceived the clinical interventions to be highly complex, in terms of potential barriers to implementation on multiple levels and changes required in understanding, attitudes, and behaviour among various stakeholders (205, 206). The innovations' source, evidence-base, relative advantage, and complexity are related to Proctor et al.'s (146) concept of 'acceptability'. From the discussion of these constructs above, it is clear that the clinicians found the clinical interventions generally acceptable, if somewhat complex. Previous studies and reviews have recognised that the complexity of psychosocial EBPs is an important determinant of implementation (147, 159). The overall positive experiences of patient's with the clinical interventions suggested that they also considered them acceptable (235), with the caveat that these patients were those who consented to family involvement, making their views potentially less representative.

An important determinant of implementation is 'innovation adaptability', included as construct D of CFIR domain I (139). The issue of fidelity versus adaptability is a long-standing debate within complex intervention and implementation research. A certain level of adaptability leads to increased expected scalability, but it must be done without compromising core elements and the adaptations should be clearly understood (129). However, it can be difficult to distinguish between the core elements and the 'adaptable periphery' of a complex intervention (138, 217), and its effects may arise through a synergy between elements, rather than just being the sum of the individual components' effects (135). It is also hard to balance the need for full and consistent implementation across various sites against the necessary flexibility to allow local adjustments (138), and in practice evaluators may not have control over how implementers choose to adapt the intervention (135). Some researchers have therefore suggested that necessary adjustments should be allowed, as long as they do not contradict the underlying programme theory, and that clinical judgement and tailoring is necessary to ensure a responsive delivery of the intervention (135, 217).

In the IFIP study, the implementation of basic family involvement practices alongside FPE offered clinicians the possibility to scale their family involvement up or down, depending on the patient's and the family's needs. The clinicians in Article 4 experienced that the FPE model was highly structured, while also being flexible enough to be adapted to individual patients and their families. The utility of having a structured model with room for flexible adaptations, such as FPE and similar family interventions, has been recognised by clinicians in previous qualitative studies (84, 85, 194, 239). However, Article 4 and the qualitative study on patient's experiences showed that a few patients and clinicians thought that the FPE model was too rigid to be adequately tailored (235). We also encouraged clinicians to use single elements of FPE, when it was not feasible or relevant to offer the full model. It is clear from the results of Article

4 that clinicians used single elements of FPE actively in other contexts. The qualitative implementation process evaluation further indicated that the focus on basic family involvement practices lowered the threshold for initiating family involvement in general (205). This flexible use of FPE elements is not reflected in the FPE scale fidelity results in Article 3, as these constitute ratings of model adherence when the model was offered in full. It is a possibility however, that the flexibility may have resulted in the clinicians offering single elements and BFIS practices rather than the full FPE model, which might have contributed to the differences seen between the FPE and BFIS penetration rates.

Adaptability is related to Proctor et al.'s (146) concept of 'appropriateness'. Increased adaptability allows an intervention to be fitted to the local context, rendering it more appropriate. The clinicians in Article 4 found that the clinical interventions were adaptable and compatible with their clinical mission, practice, and setting. They also considered them appropriate for patients with psychotic disorders and their relatives, although some experienced poor model fit with particular patients or families, a finding that was corroborated by the negative experiences of some patients in their qualitative study (235). In general, both the clinicians in Article 4 and the patients found the elements of the clinical interventions to be useful tools, which were relevant to patients and relatives' situation and appropriate to address challenges related to the illness (235). An important finding of the qualitative implementation process evaluation was how clinicians went from emphasising barriers and potential disadvantages to focus on solutions and potential benefits (205, 206), where a prominent barrier had been the lack of 'suitable' patients and families (205). It is an interesting finding how clinicians with experience in conducting FPE, in Article 4 and previous studies (84, 239), considered that the model was unfit for some patients and families, whereas clinicians who received training but did not practice FPE viewed the model as unfit for most of their patients (85). In their multinational study of FPE implementation, Magliano et al. (190) similarly found that the percentages of clinicians who reported 'availability of suitable families' and 'unsuitability of the approach to the needs of patients or families' as major barriers, fell from 42 to 15 % and from 32 to 7 % respectively over a one-year period. However, the percentage of clinicians who identified 'the integration of family involvement with other responsibilities' and 'the overall burden of work' as major barriers, remained high throughout the study at 43-65 % (190).

This leads us to another concept of Proctor et al. (146), which is that of 'feasibility'. While the clinicians in Article 4 considered the clinical interventions acceptable, adaptable, and appropriate, the qualitative implementation process evaluation showed how they also recognised that FPE was resource demanding, requiring two professionals to allocate time bi-weekly or monthly over an entire year or longer (205). While this barrier could be somewhat alleviated by adequate leadership commitment and prioritisation (205), the relatively modest increase in the FPE penetration rate in Article 3 might suggest that it was not feasible for the services to offer the model on a large scale, at least not after 18 months of implementation support. As indicated previously, the relatively high BFIS penetration rates might indicate that these practices were more feasible for the services to implement. Feasibility is sometimes linked to 'trialability', which is the possibility to pilot or test the intervention on a small scale, included as construct E of CFIR domain I (139). While we did not explore clinicians' perceptions of the

interventions' trialability, the whole-ward approach might be said to constitute the exact opposite of a small-scale testing or piloting. However, trialability may not be the most important characteristic when one is dealing with a well-documented intervention that is recommended in the clinical practice guidelines, such as FPE. 'Innovation design and cost', constructs G and H (139), were not discussed during the focus groups with clinicians.

Finally, an important implementation outcome listed by Proctor et al. (146) is 'sustainability'. While we did not include quantitative measures or qualitative interview questions specifically focusing on sustainability, several of our findings may be relevant to the sustainability of the clinical interventions. The organisational, structural, and procedural changes in the experimental arm, such as the appointment of a family coordinator, creation of written information material, establishing procedures, integration of family involvement with other treatment modalities, and documentation in the patients' medical records, were recorded through the BFIS and GOI scales in Article 3. These measures were intended to facilitate the implementation of family involvement, but might also be critical to ensure sustainability over time. The relatively high penetration rate of BFIS practices might also contribute to long-term sustainability, as recognised by Proctor et al. (146). Through the qualitative implementation process evaluation (205), we see that clinicians valued the organisational and procedural measures. However, they particularly emphasised how the whole-ward approach led to a change in the unit culture, as well as in the clinical practice and general awareness among professionals (205), which might contribute to the sustainability of the new practices. Finally, they also recognised that the reliance on external support for implementation, training, and supervision may render the new practices vulnerable after the project's completion (205).

In this subchapter, I have described how the clinicians in the IFIP study found the clinical interventions generally acceptable, in terms of innovation source, innovation evidence-base, and relative advantage, but also highly complex with regards to implementation and delivery. They considered that the clinical interventions were structured, but also adaptable and flexible, and the perceived flexibility may have increased the general adoption of family involvement practices, while it may also have lowered the penetration of the FPE model. The increase in clinicians' perceived appropriateness for the patient group and their relatives was linked to their practice and experience with family involvement. Clinicians reported that FPE was resource demanding, and the implementation results might indicate that BFIS practices were more feasible to implement than FPE. The structural, organisational, cultural, and clinical changes in the experimental units, which were perceived as important by the clinicians and documented through the quantitative implementation outcomes, may contribute to the sustainability of family involvement practices, but the clinicians also reflected that the reliance on external support may render these new practices vulnerable after the end of the IFIP study.

7. Implications

In this section, I will reflect on possible implications of the thesis' findings, regarding the implementation in mental health services; policy and education; clinical practice, and future research.

7.1. Implementation in mental health services, policy and education

The findings of Article 2 demonstrated an irregular and generally poor implementation of family involvement in the participating CMHC units. Although our findings concerned a specific geographical context and patient group, we have no reason to believe that the status of implementation was better in the remaining CMHCs of the country, or with regards to other patient groups and their relatives. The later Norwegian reports of poor implementation, in both specialised and municipal services (126-128), indicate that there is a need to continue the work on implementing family involvement in Norwegian mental health care.

The findings of Article 3 showed that it was possible to implement family involvement practices in CMHCs and the strategies, measures, and instruments of the IFIP study may be useful to health services and administrators who wish to scale up these practices. In particular, the BFIS scale introduced in Article 2 may prove useful to evaluate the implementation of basic family involvement practices and may be revised to cover additional patient categories and service settings. The IFIP conversation guide will be further developed by the Division of Mental Health and Addiction at Vestre Viken Hospital Trust, having received social innovation funding from the South-Eastern Norway Regional Health Authority, and will likely be available for general use in 2023-2024. The IFIP toolkit containing various measures, tools, and resources that have been developed in partnership with the participating units, will be refined and disseminated as part of a social innovation project, funded by the University of Oslo (SPARK Social Innovation).

However, it will probably be unfeasible for most services to employ the IFIP ISP in its entirety without external support, given the extensive scope of its measures. Thus, future implementation and research projects (see below) need to test scaled down versions of this programme, containing fewer and simplified strategies. The findings of the qualitative implementation process evaluation suggested that implementing a combination of basic and advanced family involvement; a special focus on the engagement phase and confidentiality; a whole-ward approach; a focus on leadership commitment, and regular audit and feedback might be critical measures to succeed with the implementation (205, 206). Article 4 also described perceived challenges and disadvantages that should be acknowledged and addressed in future implementation projects.

The CMHCs and/or health trusts may have to prioritise creating local capacities for training and supervision in family involvement, given the scarcity of such resources and the vulnerability of depending on external support. Although it was not a focus of the IFIP study, future efforts to implement family involvement will need to consider how to integrate the involvement and

support of children, adolescents, and siblings as relatives, in order to provide comprehensive family involvement services. The mental health services will also need to find an appropriate balance, between digital/eHealth interventions and face-to-face family involvement and support.

At the policy level, there is a need for increased financial incentives to conduct family involvement in Norwegian mental health services. The health authorities should also make plans for how guidelines and EBPs will be implemented efficiently in the services. During the IFIP study, we discovered how family involvement was not adequately taught in the professional education of health personnel in Norway. Considering the substantial resources and effort necessary to implement these practices directly in the health services, it would be more efficient to teach family involvement in the basic education and/or specialisation of mental health professionals.

7.2. Clinical practice

The findings of Article 4 showed how the clinicians in our study generally perceived that family involvement in the treatment of persons with psychotic disorders was beneficial to the patients, the relatives, and themselves. Their descriptions of the processes involved might indicate that a joint focus on basic and advanced family involvement practices was appropriate, allowing for clinical judgement and adaptations to the service context and to the individual patients and their families. It was clear from the qualitative implementation process evaluation however, that clinicians needed to experience these benefits first-hand (205).

Furthermore, the clinicians in Article 4 reported that it was particularly important for the relatives to understand the negative symptoms experienced by the patient, in order to attribute these to the illness rather than to negative personal characteristics. The identification of important clinician-facilitated elements, by the participants of this study, may aid other clinicians in prioritising the most essential practices when conducting family involvement. These findings concerned a specific patient group in a specific clinical, cultural, and geographical context, but the clinical interventions used and the general insights generated may be relevant to patients with other forms of severe mental illness (59, 60) and in other sociocultural contexts (247).

7.3. Future research

As mentioned above, future research needs to test scaled-down and simplified versions of the substantial implementation support provided in this study, to identify efficient measures to scale up family involvement practices in mental health services. It will be necessary to compare implementation strategies through randomised designs, to generate systematic evidence on their relative effectiveness. There is also a need for research on the sustainability of family involvement practices over time, as well as research on implementation in other service settings,

such as municipal services and inpatient units, and for patients with other forms of severe mental illness.

The BFIS scale can be used in future research, but should be revised, re-piloted, and accompanied by a fidelity review manual. Future implementation studies that employ formative evaluation should develop more feasible and sustainable audit and feedback strategies, such as simpler self-assessment instruments, but also investigate technological and digital assessment solutions. There is a balance between creating brief and pragmatic instruments on the one hand and rigorous and precise on the other, depending on their intended use in either clinical practice or research (148). Simpler self-assessment instruments for formative evaluation through audit and feedback can be combined with more thorough fidelity assessments for summative evaluation, to investigate the feasibility and effectiveness of implementation strategies without external support.

Quantitative studies are also needed to test the relationships between implementation outcomes and the effects of specific implementation determinants. Different implementation outcomes might be important to the various stakeholders (146) and researchers should focus on those that answer the needs of central decision-makers and stakeholders.

The IFIP study demonstrated the value of a mixed methods process evaluation and future implementation studies should formulate a programme theory to identify the most critical knowledge gaps, to focus the process evaluation properly. Future qualitative studies of family involvement should investigate further the processes, potential critical elements, and mediating factors of family involvement in general, and for specific family interventions such as FPE. These qualitative studies should include the perspectives of all the relevant stakeholders.

8. Conclusion

The aim of the IFIP study was to improve the cooperation between patient, relative, and clinician, as well as the psychosocial health of patients and adult relatives, by implementing the national guidelines on family involvement for persons with psychotic disorders in Norwegian CMHCs. The IFIP project group developed a comprehensive ISP and the complex IFIP intervention, to operationalise and support the implementation of the national guidelines in participating CMHCs. The processes and effectiveness of clinical and implementation interventions were evaluated through a hybrid effectiveness-implementation cluster randomised and mixed methods design, where the experimental clusters received the ISP for 18 months. Both interventions and evaluations targeted the organisational and clinical level, and data were collected from all the central stakeholders. This thesis included large parts of the implementation and clinical process evaluations, as well as the implementation effectiveness evaluation, based on data from clinicians and their CMHC units.

At baseline, the participating CMHCs lacked organisational structures, standardisation, and procedures for family involvement, and few patients with psychotic disorders and their relatives had been provided with basic family involvement practices or FPE. The project achieved a significant increase in the fidelity to and penetration of both BFIS and FPE in the experimental arm, when compared to the control arm, with adequate fidelity to these clinical interventions in all experimental clusters. Thus, the ISP had a significant and substantial effect on the level of adherence to the national guidelines, when compared to no such implementation support. Although the increase in the FPE penetration rate was significant in the experimental arm, the rate was still quite low. A qualitative explorative study of clinicians' perceptions of family involvement in the treatment of persons with psychotic disorders, showed that they mainly experienced benefits for all the central stakeholders. It further described how clinicians perceived these benefits as highly interconnected and linked to specific elements facilitated by health professionals. Perceived challenges and disadvantages were also reported, but with a higher variety and lower frequency than the benefits.

If we compare with previous studies on the implementation of family involvement in mental health services, the implementation results of the IFIP study were very good. The qualitative results both complemented and corroborated the findings of previous studies on stakeholders' experiences with family involvement. Clinicians' perceptions of the clinical interventions' characteristics may have influenced the implementation outcomes, such as fidelity and penetration. Despite the limitations of the study design and evaluation methods, sometimes resulting from limited time, resources, and staffing, the interventions, measures, instruments, and findings of the IFIP study should be highly relevant to policy makers, administrators, health services, and clinicians who wish to implement family involvement practices in mental health services. Future research should focus on identifying efficient measures to scale up family involvement, while conducting mixed methods process evaluations of high quality.

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Appendices and publications

Appendix 1 Informed consent form for implementation teams

Appendix 2 Informed consent form for ordinary clinicians

Appendix 3 Interview guide for focus groups with implementation teams

Appendix 4 Interview guide for focus groups with ordinary clinicians

Appendix 5 The Basic Family Involvement and Support (BFIS) scale

Article 1 Hestmark L, Romøren M, Heiervang KS, Weimand B, Ruud T, Norvoll R, Hansson KM, Norheim I, Aas E, Landeweer EGM, Pedersen R. *Implementation of guidelines on family involvement for persons with psychotic disorders in community mental health centres (IFIP): protocol for a cluster randomised controlled trial.* BMC Health Services Research. 2020;20(1):934. doi: 10.1186/s12913-020-05792-4

Additional file 1: The IFIP intervention.

Article 2 Hestmark L, Heiervang KS, Pedersen R, Hansson KM, Ruud T, Romøren M. *Family involvement practices for persons with psychotic disorders in community mental health centres - a cross-sectional fidelity-based study.* BMC Psychiatry. 2021;21(1):285. doi: 10.1186/s12888-021-03300-4

Article 3 Hestmark L, Romøren M, Heiervang KS, Hansson KM, Ruud T, Šaltytė Benth J, Norheim I, Weimand B, Pedersen R. *Implementation of Guidelines on Family Involvement for Persons with Psychotic Disorders (IFIP): A Cluster Randomised Controlled Trial.* Administration and Policy in Mental Health and Mental Health Services Research. 2023;50(3):520-33. doi: 10.1007/s10488-023-01255-0

Additonal file 2: Timeline for the experimental clusters.
Additional file 3: Adjustment for stratification variable.
Correction: Correction to table 3.

Article 4 Hestmark L, Romøren M, Hansson KM, Heiervang KS, Pedersen R. *Clinicians' perceptions of family involvement in the treatment of persons with psychotic disorders: a nested qualitative study.* Frontiers in Psychiatry. 2023;14:1175557. doi: 10.3389/fpsyt.2023.1175557

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET – VERSJON 23.12.2019

BEDRE PÅRØRENDESAMARBEID (BPS)

OM STUDIEN

Dette er et spørsmål til deg om å bidra inn i prosjektet «Bedre pårørendeSamarbeid (BPS)». Målet med dette prosjektet er å bedre samarbeidet mellom ansatte, pasient og pårørende og å bedre helsen til pasienten og deres pårørende. Vi ønsker å lære mer om pårørendesamarbeid sett fra ulike perspektiv; pasienter, pårørende og helsepersonell som jobber med psykosepasienter. Du er invitert til å delta i prosjektet fordi du representerer en av disse gruppene.

Det er 14 DPS (distriktpsykiatriske sentre)-enheter som deltar i prosjektet i tillegg til det behandlingsstedet der du er ansatt. Alle disse stedene vil få hjelp til å bedre samarbeidet med pårørende; først den ene halvparten (intervensjonsgruppen), så den andre halvparten (kontrollgruppen). Det skal bare fokuseres på tiltak som både er anbefalt og som er vist å være bra for pasienten og de pårørende. Eksempler på slike tiltak er å opprette en pårørendekoordinator og å gi de ansatte opplæring slik at pasienter og pårørende kan få informasjon, opplæring og oppfølging som er godt tilpasset deres behov.

Prosjektet er et samarbeid mellom Universitetet i Oslo, Akershus universitetssykehus HF, OsloMet, TIPS Sør-Øst og de deltakende behandlingsstedene. Dette er en multisenterstudie hvor Universitetet i Oslo er koordinerende institusjon med prosjektledelse og hvor Universitetet i Oslo, OsloMet, Akershus universitetssykehus HF, Vestre Viken HF, Sykehuset i Vestfold HF, Diakonhjemmet, Sykehuset i Telemark HF, Oslo Universitetssykehus HF, Helse Fonna HF og TIPS Sør-Øst er dataansvarlige/forskningsansvarlige institusjoner. Forventet prosjektslutt er 1. oktober 2027.

HVA INNEBÆRER DELTAGELSE I GRUPPEINTERVJUET?

Din deltagelse innebærer at du deltar i et gruppeintervju sammen med andre ressurspersoner i forbedringsteamet fra din enhet. To forskere vil gjennomføre intervjuet i forbindelse med enhetens veiledningsdag januar 2020. Hvert intervju vil ta ca. 1,5 time.

Temaer vi ønsker å spørre dere i forbedringsteamet om:
Erfaringer med pårørendesamarbeidet og å delta BPS, inkludert implementeringsstøtten og arbeidet i forbedringsteamet.

- De viktigste hemmerne og fremmerne i pårørendesamarbeidet, inkludert etiske dilemmaer.
- Betydningen av pårørendesamarbeidet.

For å være sikker på at vi får med alt gruppen sier, ønsker vi å bruke lydopptaker. Forskerne vil ta ansvar for å utelate all informasjon som kan identifisere deg og andre personer i publisering og formidling fra prosjektet. Lydopptakene vil bli overført til en sikker server (TSD) og skrevet ut av forsker eller assistent uten identifiserbare kjennetegn.

Nedenfor ber vi deg fylle ut informasjon om alder og stilling, samt kontaktinformasjon. Dette vil bli oppbevart separat fra lydfiler og transkripsjoner.

MULIGE FORDELER OG ULEMPER

Det er ingen ulemper for deg utover det å bruke tid på å delta i intervjuet. Prosjektet skal bidra til bedre samarbeid mellom ansatte, pasient og pårørende ved alvorlig psykiske problemer, og gi mer kunnskap om hvordan en kan få til bedre behandling. Et viktig mål med studien er å bidra til helsetjenester som i enda større grad forstår og ivaretar også de pårørendes behov. Pasienter og pårørende på tjenestesteder som deltar i prosjektet vil få samme eller bedre hjelp enn de ellers ville fått.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du har også rett til å få informasjon om utfallet/resultatet av studien.

Du kan når som helst og uten å oppgi noen grunn trekke deg fra prosjektet. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder Reidar Pedersen: reidar.pedersen@medisin.uio.no, telefon: 22 84 46 63/41 57 59 87.

HVA SKJER MED INFORMASJONEN VI SAMLER?

Intervjuene skal kun brukes slik som beskrevet over. Samtykkeskjema, lydfiler og intervjuutskrifter vil alle oppbevares hver for seg. Alle data anonymiseres senest innen 5 år etter prosjektslutt.

Det er kun forskere tilknyttet prosjektet som har tilgang til dataene og de er underlagt taushetsplikt. Alle data vil lagres på en sikker server (TSD) ved Universitetet i Oslo i prosjektperioden. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Vi vil gjerne oppbevare kontaktinformasjonen din i inntil 5 år for å kunne ta kontakt med deg hvis det skulle bli behov for innhente supplerende informasjon senere.

Resultater fra studien vil munne ut i noen anbefalinger om fremtidig politikk- og lovutvikling, samt systemutvikling av det psykiske helsefeltet for å styrke pårørendesamarbeid og implementering av Pårørende-veilederen. Resultatene fra studien vil også presenteres i vitenskapelige forskningsartikler, populærvitenskapelige tidsskrift eller i undervisning og foredrag. Du har også rett til å få informasjon om utfallet/resultatet av studien.

UTLEVERING AV OPPLYSNINGER TIL ANDRE

Det er ikke aktuelt å utlevere hverken direkte eller indirekte identifiserbare opplysninger til andre. Anonymiserte opplysninger og forskningsresultater vil bli brukt slik som angitt ellers i dette skrivet.

GODKJENNING

Prosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk (REK):
Saksnr. 2018/128, dato: 29.05.2018.

Personvernombudets ved XX HF's tilrådning: XX Kontaktinfo: XX

Brudd på personvernregelverket kan klages inn til Datatilsynet; Postboks 458 Sentrum, 0105 Oslo.

Det rettslige grunnlaget for gjennomføringen av prosjektet er personvernforordningens artikkel 9 nr. 2 bokstav a, samt personopplysningslovens § 10.

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Sted og dato

Deltakers signatur

Deltakers navn med store bokstaver

Alder: _____

Stilling: _____

Kontaktinformasjon:

Telefonnummer: _____

E-postadresse: _____

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET - VERSJON 31.03.2020

BEDRE PÅRØRENDESAMARBEID (BPS)

OM STUDIEN

Dette er et spørsmål til deg om å bidra inn i prosjektet «Bedre pårørendesamarbeid (BPS)». Målet med prosjektet er å bedre samarbeidet mellom ansatte, pasient og pårørende og å bedre helsen til pasienter og deres pårørende. Vi ønsker å lære mer om pårørendesamarbeid sett fra ulike perspektiv; pasienter, pårørende og helsepersonell som jobber med pasienter med psykoselidelser.

Det er 14 DPS(distriktpsykiatriske)-enheter som deltar i prosjektet i tillegg til det DPS-et der du er ansatt. Alle disse stedene vil få hjelp til å bedre samarbeidet med pårørende; først den ene halvparten (intervensjonsgruppen), så den andre halvparten (kontrollgruppen). Det skal bare fokuseres på tiltak som både er anbefalt og som er vist å være bra for pasienten og de pårørende. Eksempler på slike tiltak er å opprette en pårørendekoordinator og å gi de ansatte opplæring slik at pasienter og pårørende kan få informasjon, opplæring og oppfølging som er godt tilpasset deres behov.

Prosjektet er et samarbeid mellom Universitetet i Oslo, Akershus universitetssykehus HF, OsloMet, TIPS Sør-Øst og de deltakende behandlingsstedene. Dette er en multisenterstudie hvor Universitetet i Oslo er koordinerende institusjon med prosjektledelse og hvor Universitetet i Oslo, OsloMet , Akershus universitetssykehus HF, Vestre Viken HF, Sykehuset i Vestfold HF, Diakonhjemmet, Sykehuset i Telemark HF, Oslo Universitetssykehus HF, Helse Fonna HF og TIPS Sør-Øst er dataansvarlige/forskningsansvarlige institusjoner. Forventet prosjektslutt er 1. oktober 2027.

HVA INNEBÆRER DELTAGELSE I GRUPPEINTERVJUET?

Din deltagelse i prosjektet innebærer at du deltar i et gruppeintervju sammen med 4-8 ansatte ved din avdeling/enhet. Vi vil spørre deg og de andre deltagerne om deres synspunkter på- og erfaringer med hvordan pårørende til alvorlig psykisk syke personer involveres. To forskere vil gjennomføre intervjuet som en del av en veiledningsdag høsten 2020. Intervjuet vil ta ca. 1,5 time. Av smittevernhensyn kan intervjuet om nødvendig måtte gjennomføres via en godkjent digital løsning med videomulighet og eventuelt utenom veiledningsdagen.

Temaer vi ønsker at du/gruppen skal si noe om:

- Hvordan er arbeidet med pasienter og deres pårørende ved deres enhet i dag?
- Hva opplever dere er viktig for å bedre familiearbeid?
- Hvilke utfordringer har dere i møte med pårørende?
- Er pårørendearbeidet hos dere bedret av intervensjonen (prosjektet)?
- Har prosjektet ført til at pasienter eller pårørende har fått det bedre?
- Har dere tilbakemeldinger på hva som fungerer, eventuelt ikke fungerer hos dere?
- Spesielt for den pågående Corona-pandemien: Hvordan har epidemien påvirket behandling, oppfølging og pårørendesamarbeid hos dere? Eksempler på gode tiltak?

For å være sikker på at vi får med alt gruppen sier, ønsker vi å bruke lydopptaker. Forskerne vil ta ansvar for å utelate all informasjon som kan identifisere deg og andre personer i publisering og formidling fra prosjektet. Lydopptakene vil umiddelbart bli overført til, og lagret på, en sikker server (TSD) og skrevet ut av forsker eller assistent uten direkte identifiserbare kjennetegn.

Nedenfor ber vi deg fylle ut informasjon om alder og stilling. Dette vil bli oppbevart separat fra lydfiler og transkripsjoner.

MULIGE FORDELER OG ULEMPER

Det er ingen ulemper for deg utover det å bruke tid på å delta i intervjuet. Prosjektet skal bidra til bedre samarbeid mellom ansatte, pasient og pårørende ved alvorlig psykiske problemer, og gi mer kunnskap om hvordan en kan få til bedre behandling. Et viktig mål med studien er å bidra til helsetjenester som i enda større grad forstår og ivaretar også de pårørendes behov.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke deg fra prosjektet. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder Reidar Pedersen: reidar.pedersen@medisin.uio.no, telefon: 22 84 46 63.

HVA SKJER MED INFORMASJONEN VI SAMLER?

Intervjuene skal kun brukes slik som beskrevet over. Samtykkeskjema, lydfiler og intervjuutskrifter vil alle oppbevares hver for seg. Alle data anonymiseres senest innen 5 år etter prosjektslutt.

Det er kun forskere tilknyttet prosjektet som har tilgang til dataene og de er underlagt taushetsplikt. Alle data vil lagres på en sikker server (TSD) ved Universitetet i Oslo i prosjektperioden. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Vi vil gjerne oppbevare kontaktinformasjonen din i inntil 5 år for å kunne ta kontakt med deg hvis det skulle bli behov for innhente supplerende informasjon senere.

Resultater fra studien vil munne ut i noen anbefalinger om fremtidig politikk- og lovutvikling samt systemutvikling av det psykiske helsefeltet for å styrke pårørendesamarbeid og implementering av pårørende-veilederen. Resultatene fra studien vil også presenteres i vitenskapelige forskningsartikler, populærvitenskapelige tidsskrift, eller i undervisning og foredrag. Du har også rett til å få informasjon om utfallet/resultatet av studien.

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GODKJENNING

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SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Sted og dato

Deltakers signatur

Deltakers navn med store bokstaver

Alder: _____

Stilling: _____

Kontaktinformasjon:

Telefonnummer: _____

E-postadresse: _____

Overview of topics to be covered during the interviews

Remember to ask for specific examples

Intro: Summarise the most important changes at the unit on all levels, check whether this information is correct, and then focus initially on the significance of the services that are increasingly offered to patients and relatives.

The significance of improved family involvement practices when in contact with patients and relatives (The clinical elements of the IFIP intervention: conversations, written information material, psychoeducative seminars for relatives, and family psychoeducation)

- For the patients.
- For the relatives.
- For yourself as health professionals, and the services.
- Is there anything else they should be offered?

Ethical dilemmas and conflicts of interest during family involvement, and other barriers and facilitators

- Which dilemmas/conflicts of interest have you experienced during family involvement, at the unit? (Patient vs. relatives. What roles do the clinicians' perceptions and interests play?)
- What challenges have you experienced concerning the exercise of the duty of confidentiality during family involvement?
- What challenges have you experienced with regard to receiving/documenting information from relatives?
- How were these situations handled? Could anything have been done otherwise?
- Hand out the 'barrier and facilitator' document and ask them to comment on any missing factors.
- Which measures could be useful at the administrative and policy level (health trust/national level)? (For instance legislation, financial incentives, documentation systems, more clearly stated policies on next of kin).

Experiences with the implementation effort (local implementation team, family coordinator, training, and guidance)

- The effort to implement the IFIP intervention. What works well or not so well at your unit? Possible changes? Any suggestions for other measures?
- Experiences with the implementation support program? Positive and negative experiences? Any suggestions for changes?
- Is everybody in the unit committed to the project? Understanding of responsibility: What role and responsibility towards next of kin do you consider yourself to have, as health professionals? (Are there variations related to professional background?). Any changes?
- What impact do the clinical pathways for mental health and substance abuse have on the way you practice family involvement today?
- If we have time: Standardisation versus professional autonomy – what is a good balance?

Overview of topics to be covered during the interviews

Remember to ask for specific examples

Introduction: What are the most important changes that have taken place at your unit since the project began?

- How do you notice these changes in your daily work?
- Increased competence/assurance?
- Altered ways of thinking/attitudes?
- Altered ways of working?
- Changes in the services offered to the unit's patients and their relatives?

The significance of improved family involvement practices when in contact with patients and relatives (The clinical elements of the IFIP intervention: Conversations, family psychoeducation, crisis/coping plan, written information material, psychoeducative seminars for relatives). Positive and negative experiences. Ask a general open-ended question first, and then it is possible to ask specifically about each single element.

- For yourself as health professionals.
- For the health services.
- For patients and relatives.
- Specific examples.
- Any feedback from patients and relatives?
- Possibly mention the most important documented effects of family interventions and inquire whether they have experienced these effects.
- What has worked well at their unit, and why.
- What has not worked well at their unit, and why. Ask specifically about any suggestions for changes.
- Is there anything else that patients and relatives should be offered?

Challenges related to the duty of confidentiality and documentation

- Quite a few health professionals report that they face challenges related to the duty of confidentiality during family involvement. Have you experienced such challenges? Any changes?
- During the IFIP project, we have experienced that many clinicians are unsure of where and how they should receive/document information from relatives. Have you experienced such uncertainty? Any changes?
- (*If they report challenges*) How were these situations handled? Could anything have been done otherwise?

The significance of competence development and improved structure of family involvement practices (procedures and routines, documentation, family coordinator, systematic assessments of FPE eligibility etc.) and tools/resources (e.g. the conversation guide). Positive and negative experiences. Ask a general open-ended question first, and then it is possible to ask specifically about each single measure.

- For yourself as health professionals.
- For the health services.
- Which measures/tools have worked well at their unit? Why?
- Which measures/tools have not worked well at their unit? Why? Ask specifically about any suggestions for changes.
- Are there any measures/tools that we have not prioritised, which could have been useful?

Shared understanding, leadership commitment, and the clinical pathways

- Does the local context affect these factors?
- Would you say that there is a shared understanding of why and how one practices family involvement at the unit? If so, how does this shared understanding manifest itself?
- What role would you say the leadership at the unit has played in the project/implementation work? How does this affect the implementation work?
- What impact do the clinical pathways for mental health and substance abuse have on the way you practice family involvement today?

Experiences with the coronavirus pandemic

- How would you say that the coronavirus pandemic has affected your daily work?
- Has the follow-up of patients and relatives changed? If that case how?
- Have there been challenges with the family involvement during the pandemic? Examples? If yes, how were these challenges dealt with?
- Are there any of the measures implemented as part of the IFIP trial that have worked particularly well during this crisis? Are there any of the measures that have worked poorly? Examples?
- Are there any other family involvement measures that could have been useful in relation to the crisis? Examples?

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)					
	Item **Score:**	**1**	**2**	**3**	**4**	**5**
1	**Training and supervision of health personnel** The unit shall ensure that annual training in basic family involvement and support is offered to all health personnel at the unit. The training should cover the following subjects: a) The importance of family involvement and the benefits of following the national guidelines. b) How to approach relatives in a good way, and show acknowledgment through small gestures (offer coffee/water, wish them welcome etc.). c) The legal rights and roles of patients and relatives, and the health services' obligations towards them. d) How to promote family- and patient involvement, good communication and cooperation with relative and patient in different phases and situations during the treatment of psychotic disorders. e) Common challenges related to the carer role, how health personnel can support relatives, and about support measures in and outside the health services. f) Professional, legal and ethical challenges that may arise during family involvement and strategies to handle these.	0-1 criterion	2-3 criteria	4-5 criteria	6 criteria	7 criteria

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)					
	Item **Score:**	**1**	**2**	**3**	**4**	**5**
	Access to supervision g) Health personnel at the unit shall have access to supervision in family involvement (e.g. from a family coordinator, personnel with training in family psychoeducation, reflection groups or a clinical ethics committee.)					
2	**Family coordinator - General structure and responsibilities:** a) One or more of the unit's health personnel is/are designated specifically to coordinate basic family involvement and support at the unit. A proportion of the working hours are allocated to this task. (This item counts as 2 criteria if there is allocated time to the task, or 1 criterion if a coordinator is merely appointed). b) The coordinator receives training in the role, and has access to supervision and exchange of experience annually. c) The coordinator receives training in family psychoeducation (FPE), and has access to supervision and exchange of experience in FPE annually.	0-1 criterion	2-3 criteria	4-5 criteria	6-7 criteria	8 criteria

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)					
	Item **Score:**	**1**	**2**	**3**	**4**	**5**
	d) The coordinator should have good knowledge of, and a written updated overview of, support measures in and outside the health services. e) The coordinator should have good knowledge of, and a written overview of, important barriers to family involvement and possible strategies to handle them. f) Written information about the unit's family involvement (how and why) is available and handed out routinely to patients and relatives. (The criterion is met as long as somebody at the unit takes care of this). g) Written information about useful web resources and support groups is available and handed out routinely to patients and relatives. (The criterion is met as long as somebody in the unit takes care of this).					
3	**Conversation(s) with the patient without the relative(s) present.** Can be performed by the family coordinator or other health personnel with relevant training. a) Patients at the unit get at least one consultation/conversation where family involvement is the main topic. (Counts as 2 criteria).	0-1 criterion	2-3 criteria	4-5 criteria	6-7 criteria	8 criteria

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)						
	Item	**Score:**	**1**	**2**	**3**	**4**	**5**
	b) A written guide/ checklist of items that should be covered is used. Subjects concerning family involvement that should be covered in one or more conversations with the patient alone: c) Ask the patient: “What is important for you to talk about regarding family involvement?” d) Ask how the patient experience the relationship to his/her relatives, including any children. e) Investigate whether the patient is exposed to violence and/or abuse from his/her relatives. f) Talk with the patient about family involvement, confidentiality, and conflicts of interest, and elicit the patient’s preferences and concerns. g) Include issues concerning young children, their needs, and parental responsibility, (if the patient has children).						

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)					
	Item **Score:**	**1**	**2**	**3**	**4**	**5**
4	**Conversation(s) with the relative(s) without the patient present.** Can be performed by the family coordinator or other health personnel with relevant training. a) Relatives are invited to a separate conversation, to talk about family involvement and other relevant subjects. (Counts as 2 criteria). b) A written guide/ checklist of items that should be covered is used. Subjects concerning family involvement that should be covered in one or more conversations with the relative(s) alone: c) Ask the relative(s): "What is important for you to talk about?" d) Talk with the relative(s) about relevant roles, responsibilities, and legal regulations, e.g. related to family involvement, confidentiality and documentation. e) Ask how the relative(s) experience the relationship to the patient. Listen to the relatives' concerns and elicit what they already know about the patient.	0-1 criterion	2-4 criteria	5-6 criteria	7-8 criteria	9-10 criteria

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)					
	Item **Score:**	**1**	**2**	**3**	**4**	**5**
	f) Identify the relatives' tasks, resources, and carer burdens to be able to assess their need for support, and advise them on where they may get it. g) Talk with the relative(s) about common economic, social and health-related challenges related to the carer role, and about strategies to handle them and where one can get further support if necessary. h) If children are affected, talk with the relatives about the parental role and responsibilities, what information and follow-up the children need and have received, and give advice about where one can get help to meet the children's needs. i) Investigate whether the relative(s) is/are exposed to violence and/or abuse from the patient.					

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)					
	Item **Score:**	**1**	**2**	**3**	**4**	**5**
	Item 5-13: **Basic family involvement and support, measured by penetration rate. (Can be taken care of by the family coordinator and/or other health personnel with relevant training).**					
5	Ensure that personnel identify and document who are the patient's relatives (the next of kin, other central persons and additional network). The percentage of patients for whom this is done.	0-19%	20-39%	40-59%	60-79%	80-100%
6	Patients at the unit get at least one consultation/ conversation where family involvement is the main topic. The percentage of patients for whom this is done.	0-19%	20-39%	40-59%	60-79%	80-100%
7	Ensure that the subject family involvement is discussed in one or more conversations. The percentage of patients for whom this is done.	0-19%	20-39%	40-59%	60-79%	80-100%
8	Ensure that the relative(s) is/are invited to at least one conversation, without the patient present, to discuss family involvement, family psychoeducation, and other relevant subjects. The percentage of patients whose relatives have been invited to at least one such conversation.	0-19%	20-39%	40-59%	60-79%	80-100%
9	Ensure that patients and their relative(s) are invited to at least one joint conversation, preferably as a part of family psychoeducation, to share what can be shared and sum up. The percentage of patients (with their relatives) that have been invited to at least one such conversation.	0-19%	20-39%	40-59%	60-79%	80-100%

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)					
	Item **Score:**	**1**	**2**	**3**	**4**	**5**
10	The patient's primary clinician attends at least one joint conversation with patient and relative(s). The percentage of patients that have been invited to at least one such conversation with their relative(s) and primary clinician.	0-19%	20-39%	40-59%	60-79%	80-100%
11	A crisis plan/ coping plan is developed (it should be updated annually and found easily accessible in the patient records). The percentage of patients that have an applicable crisis/coping plan.	0-19%	20-39%	40-59%	60-79%	80-100%
12	Psychoeducative seminars/ information meetings for relatives, with relevant content, are arranged at least once a year. The percentage of patients whose relatives are invited to/ informed about such a seminar.	0-19%	20-39%	40-59%	60-79%	80-100%
13	The family involvement performed is summed up in the patient's discharge report to the municipal health- and care services. (Not just who is the next of kin, but what has been accomplished and agreed, information about the crisis plan, and any advice/plan for further family involvement. It should also be documented when family involvement has not been performed and why). The percentage of patients for whom this is done.	0-19%	20-39%	40-59%	60-79%	80-100%

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)					
	Item **Score:**	**1**	**2**	**3**	**4**	**5**
14	**Implementation measures** a) An implementation team, which includes the unit leader, is established at the unit to improve family involvement practices. (The leader does not necessarily have to be part of the team, but must have regular contact with the team). b) The implementation team has routines to get input from patients and relatives. c) Regular evaluation of the implementation process is performed, and the results are used actively to manage improvements. (E.g. fidelity measurements or other forms of systematic monitoring/internal control). d) Regular evaluation of how both patients and relatives experience their involvement at the unit is performed, and the results are used actively to manage improvements. (E.g. annual questionnaires or focus groups). e) The unit and the implementation team has a written overview of common barriers to family involvement, including ethical and legal dilemmas on different levels, and possible strategies to handle them. This overview, with strategies, is available and used to support the implementation.	0-1 criterion	2 criteria	3 criteria	4 criteria	5 criteria

	Appendix 5: Fidelity scale for Basic Family Involvement and Support (BFIS)						
	Item	**Score:**	**1**	**2**	**3**	**4**	**5**

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BMC Health Services Research

STUDY PROTOCOL Open Access

Implementation of guidelines on family involvement for persons with psychotic disorders in community mental health centres (IFIP): protocol for a cluster randomised controlled trial

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Abstract

Background: Family involvement for persons with psychotic disorders is under-implemented in mental health care, despite its firm scientific, economic, legal and moral basis. This appears to be the case in Norway, despite the presence of national guidelines providing both general recommendations on family involvement and support in the health- and care services, and specific guidance on family interventions for patients with psychotic disorders. The aim of this project is to improve mental health services and the psychosocial health of persons with psychotic disorders and their relatives, by implementing selected recommendations from the national guidelines in community mental health centres, and to evaluate this process.

(Continued on next page)

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Acronym for the study's short title: Implementation of Family Involvement for persons with Psychotic disorders.
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(Continued from previous page)

Methods: The trial is cluster randomised, where 14 outpatient clusters from community mental health centres undergo stratified randomisation with an allocation ratio of 1:1. The seven intervention clusters will receive implementation support for 18 months, whereas the control clusters will receive the same support after this implementation period. The intervention consists of: 1. A basic level of family involvement and support. 2. Family psychoeducation in single-family groups. 3. Training and guidance of health care personnel. 4. A family coordinator and 5. Other implementation measures. Fidelity to the intervention will be measured four times in the intervention arm and two times in the control arm, and the differences in fidelity changes between the arms constitute the primary outcomes. In each arm, we aim to include 161 patients with psychotic disorders and their closest relative to fill in questionnaires at inclusion, 6 months and 12 months, measuring psychosocial health and satisfaction with services. Clinicians will contribute clinical data about patients at inclusion and 12 months. Use of health and welfare services and work participation, for both patients and relatives, will be retrieved from national registries. We will also perform qualitative interviews with patients, relatives, health care personnel and leaders. Finally, we will conduct a cost-effectiveness analysis and a political economy analysis.

Discussion: This project, with its multilevel and mixed methods approach, may contribute valuable knowledge to the fields of family involvement, mental health service research and implementation science.

Trial registration: ClinicalTrials.gov Identifier NCT03869177. Registered 11.03.19.

Keywords: Family intervention, Psychotic disorders, Schizophrenia, Family psychoeducation, Family involvement, Mental health service research, Clinical ethics, Implementation

Background

There are compelling reasons to intensify the implementation of family involvement in mental health care, particularly for persons with severe mental illness. This study limits its scope to psychotic disorders [1], which are characterised by severe, enduring symptoms and functional and social challenges, affecting the psychosocial health, coping abilities and communication patterns of both patients and their families [2, 3].

We intend the terms 'family' and 'relative' to cover anyone who provides substantial and unpaid support to a person with a psychotic disorder, including friends and other significant persons. The concept 'family involvement' comprises both a basic level of involvement and support and family interventions, such as family psychoeducation [4]. The basic level includes meeting the relatives, assessing their strengths, burdens and needs, establishing a system of safety (crisis plan), listening to their experiences, concerns and preferences, receiving their information about the patient and providing them with general information about the health service, the illness and where they can obtain further support [5]. This necessary foundation may also constitute the initial phase of family psychoeducation, where the patient and relatives can develop coping strategies and helpful communication patterns [4].

Research indicates that family interventions may improve social function, self-experienced health and adherence with medication, as well as reduce the frequency of relapse, hospital admissions and days spent in hospital for persons with psychotic disorders [6–10]. Evidence also suggests that such interventions may improve the experience of caregiving, the quality of life among family members and family function, and further reduce the family burden, levels of 'expressed emotion' and relatives' psychological distress [6, 11–15]. Economic analyses, of family-based interventions versus standard care only, consistently report net saving in direct or indirect costs [6]. Family psychoeducation has the most solid evidence-base among these interventions [2] and is highly compatible with other pillars of psychiatric treatment, including antipsychotic medication and cognitive-based therapy. However, various family interventions have several elements in common, even if deriving from contrasting philosophical and therapeutic traditions [16].

We also consider it a moral imperative to involve those providing unpaid care and support, in collaboration with professional care. The deinstitutionalisation of mental health care services in high-income countries has led to an increase in caring responsibilities for relatives, and their efforts are estimated to save the public health services significant costs [11]. Yet, regardless of the documented benefits and a broadly acknowledged ethical and legal rationale, studies indicate that family caregivers for persons with severe mental illness experience less involvement, cooperation and support than they feel is adequate [17]. The poor implementation of family interventions in mental health care points to a similar tendency [18, 19]. This may be due to both specific barriers to implementing family involvement in mental health care, and barriers that are more general to translating evidence-based treatment into everyday clinical practice [18, 20–22].

Health authorities in several countries have attempted to bridge the gap between scientific evidence and clinical

practice by launching guidelines that recommend family interventions as a first-line treatment during all stages of psychotic disorders [23–26]. Such clinical guidelines are based on evidence synthesis from individual studies, where skilled and motivated clinicians provide an intervention to study participants, who may be carefully selected through narrow inclusion and exclusion criteria. Yet, to implement these guidelines in everyday practice, non-selected clinicians are supposed to change their clinical practice towards unselected patients and families with various comorbidities. The pathway from evidence generation to evidence synthesis and guideline development is well developed, whereas the pathway from evidence-based guidelines to evidence-based practice has more recently come to attention.

In Norway, the Directorate of Health has launched national guidelines on families/next of kin in the health- and care services. These are general recommendations on family involvement and support based on ethical considerations, legal regulations, research evidence and discussions between key stakeholders and experts [27]. Additionally, the national guidelines on the treatment of psychotic disorders and the newly launched clinical pathways in mental health care specifically recommend family interventions as a first-line treatment of psychotic disorders [28, 29]. Preliminary mapping indicate that the implementation of these guidelines vary considerably in Norwegian community mental health centres (CMHCs). However, we know little about whether implementing the national guidelines in a naturalistic setting would be associated with improved outcomes for patients, relatives and the public health and welfare services.

Within this context, our project group will develop, conduct and evaluate a complex intervention [30] to implement guidelines on family involvement for persons with psychotic disorders in Norwegian CMHCs. Through a pragmatic trial design, we will employ mixed methods to investigate and explore the implementation process in a naturalistic setting. Fidelity scales will be used to assess and influence the implementation, inspired by the groundbreaking work of the US National Evidence-Based Practices (NEBP) project and its Norwegian counterpart 'Bedre psykosebehandling' (BPB), both large-scale studies on the implementation of evidence-based practices for persons with psychotic disorders [31, 32]. Our implementation support will target a wide spectrum of clinical outpatient units and their non-selected personnel, while we measure and compare changes in implementation-, service- and client outcomes, between intervention and control sites. To study this particular intervention, a cluster-randomised design is appropriate and necessary to minimise contamination.

Objectives

Primary objective

- To evaluate whether our implementation support is associated with a higher level of implementation of the selected recommendations in the national guidelines.

Secondary objectives

- To measure the current level of implementation of the selected recommendations in the national guidelines in participating clinical units.
- To explore barriers to and facilitators for implementing the national guidelines among the stakeholders at the clinical, organisational, and policy level.
- To explore moral dilemmas and conflicting interests related to family involvement, and strategies on how to resolve them.
- To investigate whether a higher level of implementation of the selected recommendations is associated with improved outcomes for patients and relatives.
- To analyse whether outcomes for patients, relatives and the public health and welfare services, justify the costs of implementing family involvement for persons with psychotic disorders.

Trial design

The study is a cluster randomised controlled trial, employing stratified randomisation with an allocation ratio of 1:1 within each block. The clinical outpatient unit(s) with the main responsibility of treating patients with psychotic disorders, in their discrete geographical catchment area, will constitute a single cluster and unit of randomisation. Please see Fig. 1 for a general overview of the study design. This article conforms to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [33].

Methods

Setting

We selected five counties in the South-Eastern Norway Regional Health Authority to limit travel distances and the use of project resources. The selected counties had 16 CMHCs (In Norwegian 'Distriktspsykiatrisk Senter (DPS)'), which were composed of both inpatient and outpatient units. Of these 16 centres, 12 agreed to participate in the study. The main reason given for non-participation was the lack of capacity to engage in a research project. Preliminary mapping indicate major differences, both between and within centres, in the level and character of family involvement. Furthermore, the

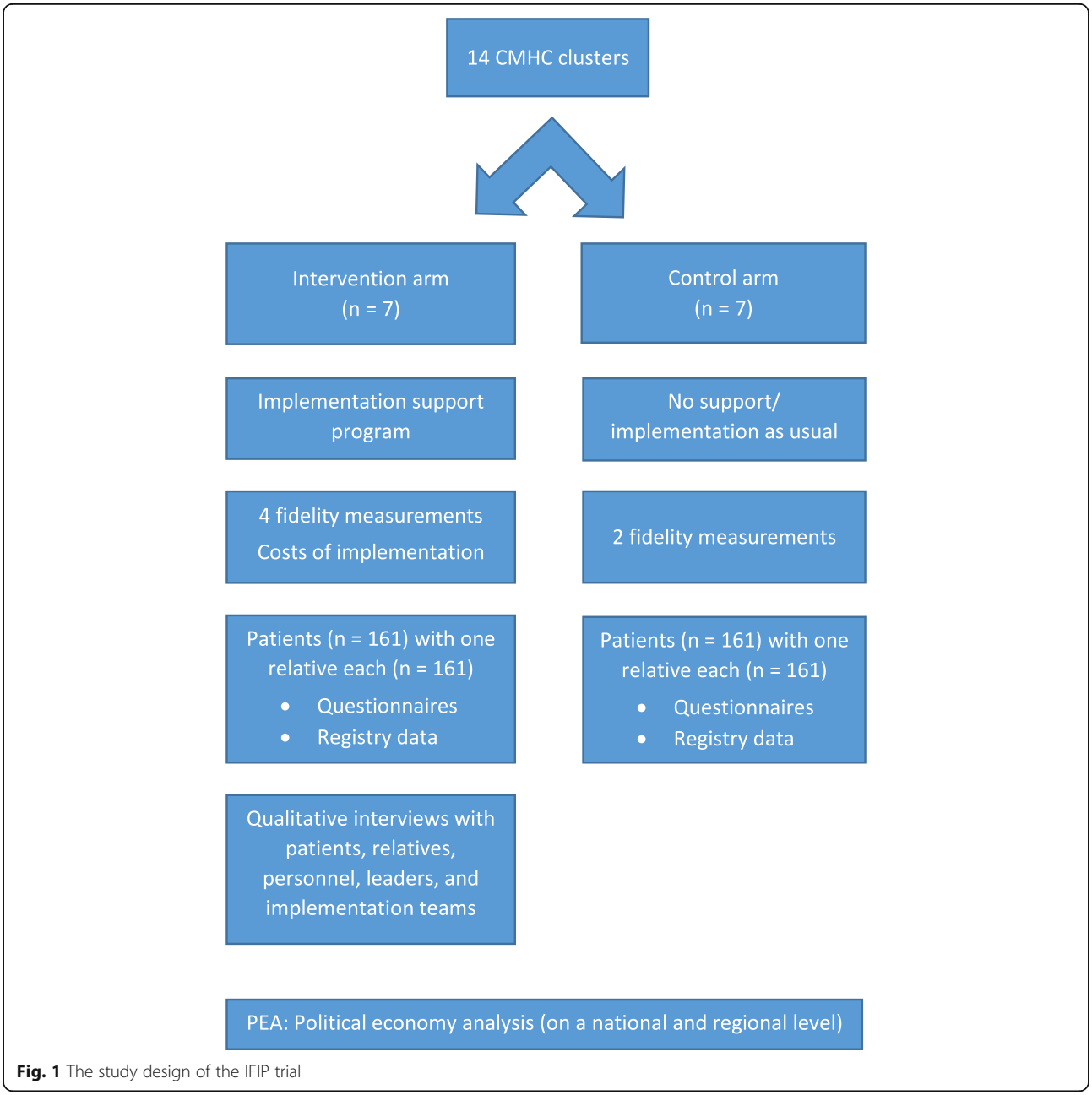

Fig. 1 The study design of the IFIP trial

distinct populations covered by the various centres show substantial differences in size, ethnic composition and median income level. A comprehensive list of study sites is available at clinicaltrials.gov.

Selection, sample size and allocation of clusters

To be eligible as clusters, clinical outpatient units had to be part of a participating CMHC and have the main responsibility of treating patients with psychotic disorders in their discrete geographical catchment area. We accepted all types of clinical outpatient units, from Flexible Assertive Community Treatment teams (FACT) [34] to stationary outpatient clinics. The study recruited both clinics solely dedicated to the treatment of psychotic disorders and units covering a wider spectrum of conditions, including substance abuse and bipolar disorder. Some of the centres had multiple outpatient units caring for patients with psychotic disorders. When these covered the same area, we invited all of them to participate in the same cluster. After having recruited 15 clinical units in total, the project had to join two of them in order to have 14 clusters for randomisation. We merged the two units who collaborated the most into a single cluster, and these came from different CMHCs. In line

with the pragmatic nature of the trial, there were no exclusion criteria for clusters.

Based on the average results from the NEBP project [31] and similar research we used a mean difference in fidelity scores of 1.82 with an average standard deviation (SD) of 0.80, after 18 months of implementation support to calculate sample size [35, 36]. Choosing 5% two-tailed significance and 80% power, we estimated that 4 clusters in each arm were needed to show that implementation support gives a significant increase in fidelity, compared to baseline or low fidelity. Since these previous studies were not randomised, a premise for this calculation is that the mean fidelity will not change in the control arm. To secure sufficient power in the quantitative study on patients and relatives (see below), we recruited 7 clusters to each arm.

The project group generated a sequence by ranking the clusters from 1 to 14, according to their current number of patients with psychotic disorders. We then stratified the clusters into three blocks; 4 clusters with between 130 and 217 patients, 6 clusters with between 60 and 129 patients, and 4 clusters with between 1 and 59 patients. Within each block, the clusters were randomised to either the intervention or the control arm, with an allocation ratio of 1:1. An independent statistician performed the allocation, drawing 14 numbers using the Microsoft Excel RAND-function, being blind to both the sequence of clinical units and the stratifying variable. The purpose of doing stratified randomisation was primarily to achieve a balance in the number of patients and relatives between the two arms, and secondly to include units of various sizes in both. Since the larger units are located in metropolitan areas, the stratification inadvertently resulted in both urban and rural clusters in each arm.

Interventions

The clinical units in the intervention arm will receive implementation support for 18 months to assist the implementation of selected recommendations in the national guidelines. The control units will receive training and guidance only after this period. Meanwhile, control sites will not be obligated to follow any specific practice. Since the IFIP intervention is a complex intervention, this section is structured after the Medical Research Council (MRC)'s framework to give a clear overview [30]. The framework was used actively to guide the development- and feasibility-stages described below.

Development

In the development phase, our project group selected recommendations in the national guidelines on family involvement for persons with psychotic disorders based on the following non-ranked criteria: a) scientific evidence of relevant and favourable outcomes for patients, relatives, or the public health and welfare services; b) legal regulations and requirements; c) feasibility for the mental health services; and d) acceptability and relevance to patients, relatives and clinicians. We developed the IFIP intervention in conjunction with the selection of appropriate outcome measures in an interactive process to cluster the selected recommendations into key interventions [37].

Inspired by a responsive evaluation approach [38], the project group carried out an assessment by panel groups of 3–9 participants, one for each of the three main stakeholders; i.e. patients, relatives, and clinicians. Through these, we explored the acceptability, feasibility and relevance to the main stakeholders of the selected recommendations, the key interventions and the proposed outcome measures. We also appointed a stakeholder committee to give advice throughout the project. The members of this committee, and representatives of the cooperating CMHCs, were given the opportunity to review the same elements. Based on this preliminary exploration, we made significant changes both to the contents of the IFIP intervention and the outcome measures, before the start of data collection and implementation. For instance, relatives emphasised the need to speak to the patient's primary clinician, and not just the family coordinator, to be involved in treatment decisions. The intervention therefore includes at least one meeting between the primary clinician, patient and relative(s). Family workers were concerned that family involvement would remain their exclusive domain and not be adopted by all clinicians as a standard approach. Thus, the intervention and implementation strategy employs a whole-ward approach, where all clinicians will be offered training in basic family involvement and FPE. A few psychometric instruments in the questionnaires were substituted by other measures because the respondents found them stigmatising and/or not accurate in addressing their situation.

The resulting IFIP intervention consists of the following elements (see Additional file 1):

I. Clinical interventions
   1.1 A basic level of family involvement and support
   1.2 Family psychoeducation in single-family groups
II. Implementation interventions
   2.1 Training and guidance of health care personnel
   2.2 A family coordinator
   2.3 Other implementation measures

Piloting, feasibility, evaluation and reporting

Recently the Norwegian research project BPB conducted and evaluated a large-scale implementation of family psychoeducation, among other evidence-based practices

for persons with psychotic disorders, employing fidelity scales and questionnaire-based outcomes [32]. Clinical, procedural and methodological input from that project limits our need for a full-scale pilot with correspondent evaluation and reporting, beyond the feasibility and acceptability assessments outlined above. The basic level of family involvement and support has not been tested and evaluated in a similarly rigorous way. However, we consider this element a necessary foundation for family psychoeducation and a similar model was piloted with limited, but positive, evaluation [39].

The implementation strategy

The implementation strategy will be adapted continuously in response to local requirements and conditions, as well as data and feedback from the clinical units. A comprehensive and final account of this process will therefore be available only after the implementation period is finished. Our approach is based on the groundbreaking work of the NEBP and its Norwegian counterpart BPB, adapting relevant strategies, tools and fidelity scales from these projects to suit the IFIP trial. The central components of our implementation strategy are listed as 'implementation interventions' in the IFIP intervention (2.1–2.3). Training and guidance of health care personnel and the appointment of a family coordinator are both part of the strategy to implement the clinical interventions. At the same time, the national guidelines recommend these two elements as permanent organisational structures which themselves need to be implemented. Thus, we will encourage the services to gradually assume responsibility for these elements and implement them on a permanent basis. Element 2.3 lists the remaining components of our implementation strategy, to support the implementation of both the clinical interventions and the permanent implementation interventions. The components include a focus on management commitment and support, a local implementation team, kick-off sessions, fidelity assessments with systematic feedback, work plans, network meetings, and exchange of experiences and tools (see Additional file 1). Our implementation strategy addresses all of the five major domains in the Consolidated Framework for Implementation Research (CFIR): characteristics of the program (e.g., evidence strength and quality, complexity); the outer setting (e.g., patient/relatives' needs and resources); inner setting (e.g., compatibility of the intervention with existing programs, leadership engagement); the process used to implement the program (e.g., quality and extent of planning, engagement of key stakeholders) and characteristics of individuals involved (e.g., knowledge and attitudes) [40], although we did not use this framework actively when designing the strategy.

Participants

The IFIP trial has three categories of participants: Patients, relatives, and clinicians. These will be recruited from the participating clusters to take part in the quantitative and qualitative studies described later in this article. A political economy analysis will involve further stakeholders, as detailed later.

Clinicians

Clinicians in the participating units perform a wide range of tasks in this trial. They will recruit patients and relatives, collect clinical data, and measure selected clinical outcomes. In addition, they will participate in research themselves, by taking part in fidelity assessments and qualitative interviews, or answering questionnaires. Apart from these mainly research-related activities, the clinicians in the intervention arm will also help implement and provide better family involvement for patients with psychotic disorders. There are no baseline requirements of the local staff, such as specific training, competency or professional background.

Patients and relatives

Patients and relatives will be included in dyadic pairs by the local clinicians.

Patients' inclusion criteria

- To have an established psychotic disorder (F20–29) [1] or a tentative diagnosis of psychotic disorder, certain enough to begin treatment. This need not be the patient's primary diagnosis. Clinicians do not have to use a specified instrument or procedure to diagnose the patient, but must record how the diagnosis was made.
- To be 18 years or older at the time of inclusion.

Patients' exclusion criteria

- To be sentenced to psychiatric treatment (forensic clients).
- Not being competent to consent to participation in research.
- Having completed more than five joint sessions of family psychoeducation in single-family groups (patient and relative together) or more than ten joint sessions (multiple families together) in multiple-family groups, or a similarly structured family intervention. Does not apply to participants in the qualitative studies.
- Not having any relatives or next of kin (see definition below).

Relatives' inclusion criteria

- Being a relative of a patient with a diagnosis as described above. We use the term 'relative' broadly, to signify any family member, close friend, next of kin, or other significant person who support the patient, without being a professional/paid helper.
- To be 18 years or older at the time of inclusion.

Relatives' exclusion criterion

- Having completed more than five joint sessions (patient and relative together) of family psychoeducation in single-family groups or more than ten joint sessions (multiple families together) in multiple-family groups, or a similarly structured family intervention. Does not apply to participants in the qualitative studies.

Patients and relatives must fulfill the criteria above and patients must receive treatment in a participating clinical unit at inclusion, but there are no further requirements. Recruitment of these pairs should be entirely independent from the decision to offer family involvement and other treatment. This means that recruited patients and relatives do not have to receive any specific treatment, intervention, or support during the trial period, in neither the intervention nor the control arm. Correspondingly, the patients and relatives receiving a project-backed intervention, such as family psychoeducation, do not have to participate in the study. For example, forensic clients and their relatives can benefit from family involvement, without taking part in the research. Disconnecting research from treatment in this way serves an ethical purpose, by not favoring study participants with better care. However, there is also an academic rationale: to investigate the impact of improved family involvement practices in the clinical unit on a wider group of patients and relatives, and not just those who received a particular intervention.

Outcomes

Evaluations of complex interventions usually require a complementary use of quantitative and qualitative methods, to investigate and inform the process [41]. Following Proctor et al.'s framework for implementation research outcomes, our study comprises implementation outcomes (acceptability, adoption, appropriateness, fidelity, penetration, and costs), service outcomes (efficiency, effectiveness, and patient-centeredness) and client outcomes (satisfaction, function, and symptomatology) [42].

Intervention fidelity

In this part, we seek to quantify the implementation of the selected national guidelines by employing three five-point fidelity scales, where 1 equals poor fidelity and 5 equals high fidelity. Researchers use such scales to assess and influence the implementation process based on the hypothesis that the replication of core elements, previously tested through rigorous research designs, will achieve similar outcomes [43, 44]. We use one scale to assess the practice and content of family psychoeducation (scale 1) and a general organisational index (GOI) scale (scale 2) to assess the organisation, penetration rate, and general integration of family psychoeducation in the unit's clinical practice. These scales were used in BPB and demonstrated robust psychometric properties [45, 46]. The third scale (scale 3) gives a composite assessment of structure, content, implementation, and penetration rate of basic family involvement and support. The project group developed the latter scale to measure other elements of the IFIP intervention. Thus, our fidelity instruments measure both fidelity and penetration rate, as defined by Proctor et al. [42].

Data collection

Project members will measure fidelity on site visits, by the aid of interviews with clinicians, leaders and resource-persons, as well as written material, observations, and quantitative data (e.g. the number of eligible patients who receive family psychoeducation). Each assessment team will consist of two persons to counteract bias and be able to calculate inter-rater reliability. The raters will score fidelity independently and then sort out any discrepancies to reach a consensus score. Clusters in the intervention arm will be scored at baseline, and with new assessments at 6, 12, and 18 months after the implementation start date, whereas units in the control arm will be measured at baseline and 18 months only. This is both to allocate our resources effectively and to avoid influencing the control clusters through repeated fidelity measurements.

Outcomes and data analysis

Project members scored baseline fidelity before randomisation of the clusters, to counteract experimenter bias. To complete objective three, we will examine the baseline fidelity scores and analyse their distribution in both arms, while exploring contributing factors such as cluster characteristics. We will investigate the psychometric properties of all three fidelity scales. When addressing objective two, we will compare change in fidelity to the intervention after 18 months, between the two arms, controlling for baseline fidelity and other relevant covariates. These latter changes constitute the IFIP trial's only primary outcomes. These outcomes will be reported as change in total fidelity, change in fidelity scales 1, 2, and 3 separately, and for scale 3; change in the subscale for penetration rate and change in the subscale for content,

structure and implementation, respectively. The two additional fidelity measurements in the intervention arm will help us monitor and influence the implementation process closely. We will employ analysis of variance (ANOVA) models for the statistical analysis.

Patients' and relatives' quantitative outcomes

The main purpose of this part is to determine whether a higher level of implementation of family involvement is associated with relevant and favorable outcomes for patients and relatives, as put forth in objective six.

Sample size

All the outcomes of this part are secondary outcomes. With regards to sample size however, for patients we elected the 'interpersonal relationships'-subscale from the Behavior and Symptom Identification Scale (Basis-24) (questions 4–8). This instrument covers six domains: depression/ functioning, interpersonal relationships, self-harm, emotional lability, psychosis, and substance abuse, as seen from the patient's perspective, and has shown good reliability and validity [47]. For relatives we chose the outcome 'experienced support' measured with the Carer Well-being and Support (CWS) questionnaire short version 2 part B. This part measures support from the health services, as experienced by the relative, with demonstrated good reliability. However, validity for this scale was not available, due to the lack of appropriate validating measures [48]. Since we have not found comparable studies that have published data on these instruments, we decided to use a 0.5 SD improvement (medium effect) when calculating the sample size. With 80% power and 5% two-tailed significance, we would need 64 patients and 64 relatives in each arm, in a study with individual randomisation. For our cluster randomised trial, assuming an intraclass correlation coefficient (ICC) of 0.05 and having 7 clusters in each arm, we need 112 patients and 112 relatives in each arm. Calculation is done as defined for cluster randomised trials in health services research [49, 50] and the elaboration of the CONSORT statement in relation to cluster randomised trials [51, 52]. Taking into account the possibility of a 30% drop out, we need to recruit 161 patients and 161 relatives per arm.

Recruitment

Local clinicians will assess the patients in their respective unit for eligibility and competence to consent to participate. If a patient fulfills the criteria, the clinician informs the patient about the study and, if he or she wishes to participate, obtains a written informed consent. The clinician will then ask for permission to contact the closest relative to inform and possibly include her or him. We would like to include patients and relatives in dyadic pairs, but if this proves difficult, we might include relatives and patients separately. The recruitment process will follow a written and uniform procedure in both arms, where every eligible patient is asked to participate, to counteract selection bias. The inclusion period will start 1 month before the implementation start date, and continue for 12 months. Since many patients are discharged from specialist health care services to follow-up in their local municipalities after 1–2 years, recruitment has to start after the randomisation of clusters. This is to ensure that participating patients are still in treatment when the intervention units are ready to begin implementation. The clinical units will receive financial compensation for each pair recruited, and to promote retention, patients and relatives will each receive a symbolic compensation (gift card) after completing the third questionnaire. When this manuscript was submitted, the trial was actively recruiting patients and relatives.

Data collection and outcomes

Clinicians will fill in a questionnaire with the patient's demographic, social, and clinical data at inclusion. They will also score the Global assessment of functioning scale (GAF), split versions for symptoms and functioning [53], along with the Health of the Nation Outcome Scale (HoNOS). The latter instrument contains 12 items on a 5-point Likert-scale, assessing clinical problems and social functioning with reasonable adequacy. HoNOS has been generally acceptable to clinicians who have used it, is sensitive to change or the lack of it, showed good reliability in independent trials and compared reasonably well with equivalent items in the Brief Psychiatric Rating Scales and Role Functioning Scales [54]. Both instruments will be repeated after 12 months or upon discharge. Before starting recruitment, clinicians attended a 1.5-h long course in scoring HoNOS and GAF, to improve the reliability of these measurements. In the majority of our clinical sites, GAF was in frequent use and HoNOS was familiar to some clinicians. We choose these instruments partly because of their brevity to reduce the burden on local clinicians.

At inclusion only, relatives will provide general demographic and social data about themselves, and patients will be screened for drug and alcohol abuse with the 11-item 'drug use disorders identification test (DUDIT) and the 10-item 'alcohol use disorder identification test' (AUDIT), respectively. Both self-reported instruments have shown satisfactory psychometric properties in clinical and non-clinical samples [55, 56].

Patients and relatives will fill in their respective questionnaires at inclusion, 6, and 12 months, containing the self-reported variables and instruments in Table 1. The self-reported instruments assess the psychosocial health of patient and relative, their experience of the mental health

Table 1 Self-reported variables and instruments at inclusion, 6 and 12 months

Variable	Instrument	Items	Scale[a]
Patients' self-reported outcomes			
Experience of mental health and functioning	**Basis-24** [47], The Behavior and Symptom Identification scale	24	L-5
Quality of life	**ReQoL-10** [57], The Recovering Quality of Life questionnaire	10	L-5
Perceived criticism and warmth from relative	**PCW** [58], Perceived criticism and warmth	5	L-10
Experienced shared decision making	**CollaboRATE** [59]	3	L-10
General satisfaction	**MANSA** [60], the Manchester Short Assessment of Quality of Life – first item	1	L-7
Experienced burden of mental health problems	IFIP trial question	1	L-7
Relatives' self-reported outcomes			
Experienced support	**CWS v2** [48], Carer Well-being and Support questionnaire, short version part B	18	L-4
Experience of caregiving	**ECI** [61], The Experience of Care-giving inventory questionnaire	66	L-5
Caregiver quality of life	**CarerQoL** [62], The Care Related Quality of Life questionnaire	7	L-3
Experienced shared decision making	An instrument inspired by **CollaboRATE** [59]	3	L-10
Expressed emotion	**FQ** [63], The Family questionnaire	20	L-4

[a] *L* Likert scale and number of steps for each item

services, including shared decision-making, and the emotional climate between patient and relative. The latter is a primary target for family psychoeducation, whereas the two first domains might be affected by various degrees of improved family involvement and support. At the same time points, exposure to family psychoeducation for patients and relatives, and exposure to involvement and support measures for relatives will be reported. Adherence with medication will be monitored with a single question to the patient, relative and clinician.

Number of psychiatric hospital admissions and days spent in hospital for patients will be obtained from national registries, for the period of 18 months before and 18 months after inclusion. Use of public health resources and work participation will be recorded for both patients and relatives over the same period of time, with data from national registries.

Data analysis

All analyses will be conducted on an intention-to-treat (ITT) basis. The primary analysis will be carried out by the use of generalised linear mixed models (GLMM), to test differences in outcome measures for patients and relatives between the intervention and control groups, as well as moderator effects. To investigate possible mediating factors, we will use techniques from modern causal mediation analyses. In order to take into account the trial design in which patients and relatives (level 1) are nested within treatment units (level 2), the treatment units will be included in the models as a random effect in accordance with CONSORT guidelines for cluster randomised trials [51]. Multiple imputation procedures will be used to manage missing values of individual characteristics. To assess the robustness of the findings, tests will be redone by only including the subset of patients/relatives with complete outcome data at 6 and 12 months. Tests will also be redone by only including the subset of patients/relatives who still satisfy the inclusion criteria (F20–29 diagnosis) at 12 months. To address objective six, we will investigate whether higher fidelity scores are associated with improved outcomes for patients and relatives, within the same model setup as described above.

Blinding

For obvious reasons, local clinicians and project members providing the implementation support cannot be blinded to the clinical units' allocation status. The project's researchers also contribute to the implementation program, and will accordingly neither be blinded. However, most of the data gathered by project members is either self-reported or retrieved from national registries, and therefore less susceptible to experimenter bias. Patients and relatives will not be informed about their clinical unit's allocation status until after they have agreed to participate, to counteract selection bias.

Qualitative outcomes

In this part, we seek to explore the implementation process, including barriers, facilitators, ethical dilemmas, conflicting interests and other aspects, both positive and negative, of family involvement during psychotic disorders, from multiple perspectives to address objectives 4 and 5. In addition, we will employ qualitative data to assist the implementation process directly, by identifying and dealing with barriers and ethical dilemmas.

We will conduct semi-structured interviews with members of each respective stakeholder group (patients, relatives, and clinicians), during the middle of the implementation period. For relatives, we will have 3–6 focus groups with 3–8 participants each and a similar number for clinicians, with the possibility to conduct individual or additional interviews with the same group when necessary. About 10–15 patients will be interviewed individually, with the option of having focus groups where

feasible. We will only include patients, relatives and clinicians from the intervention arm and the sampling will be purposive in the sense that we wish to have participants with different experiences of, and views on, family involvement. Relatives and patients can be recruited both through the local clinicians and from the participant pool in the patient- and relative study. We will explore the stakeholders' perspectives on current family involvement practices in their unit, the selected recommendations, barriers and facilitators, ethical dilemmas, and positive and negative experiences with family involvement and with the implementation project. The unit's implementation team (3–8 members) will form separate focus groups, one per intervention cluster, at the beginning of the implementation period and in the middle of it. These interviews will cover the same issues, but place particular emphasis on barriers, facilitators, ethical dilemmas, and the implementation process. All interviews will be recorded digitally, and written consent will be obtained from the participants.

Project members will transcribe the interviews verbatim and the main analytic strategy will be manifest qualitative content analysis, using the topics in the interview guide as a starting point for the analysis, and inspired by relevant theories from the fields of ethics, implementation- and social science. However, the analysis will also allow for emerging and latent themes through a more naïve reading of the transcribed text. In addition, the project group will seek to integrate other ethnographic kinds of qualitative data, such as field notes and document analysis to obtain a more comprehensive understanding of the implementation process, the institutional context, and the research questions.

Health economics

To meet objective seven, we will evaluate whether improved outcomes for patients and relatives are justified by the costs of implementing family involvement for persons with psychotic disorders, in a cost-effectiveness analysis. Based on this analysis, we aim to create a realistic overview of implementation costs and address possible risks associated with scaling up, such as austerity.

First, we will assess the nature and extent of costs and resources needed to enable and support family involvement. All intervention sites will be asked to register data about the costs of implementing family involvement, and further to add the implementation-related costs covered by our project. To compare the cost of systematic implementation of family involvement to 'implementation as usual' (see discussion), we will collect various baseline economic data from the clinical units, such as annual budgets, range of services, direct, indirect and investment costs of current family work, to identify the average cost of different therapeutic sessions. Variation in cost levels between centres will be accounted for by assigning a distribution to the average cost.

Second, we will perform a cost-effectiveness analysis, by comparing the costs and health outcomes for patients and relatives. The health outcome will be estimated by quality adjusted life years (QALYs), calculated from CarerQol-7D for relatives and ReQoL-10 for patients. Costs will be estimated from both a health care- and societal perspective. Health care utilisation for patients and relatives, such as hospital admissions, appointments with different health providers, length of stay/number of treatments, day care and medication use will be included in the health care perspective. In the societal perspective, informal care (caregivers time allocated to care), and production loss due to absence from work for patients and relatives will be included. Production loss among those not in the work force (unemployed, retired and at home) will be discussed.

Statistical analysis will consist of estimating the total costs and health outcomes of both systematic implementation and 'implementation as usual'. The results will be presented by the incremental cost-effectiveness ratio (ICER), defined by the incremental costs (differences in cost of systematic implementation versus 'implementation as usual') to the incremental QALYs (differences in total QALYs of systematic implementation versus 'implementation as usual'). Uncertainty will be displayed by the bootstrap method, a non-parametric approach. Based on the cost-effectiveness analysis a budget impact analysis of scaling up the intervention will be estimated.

Political economy analysis

This part of the study will explore facilitators for and barriers to successful implementation of family involvement on a broader sociocultural, institutional and political level by the use of political economy analysis (PEA), thereby addressing objective four [64, 65]. PEA is concerned with the interaction of political and economic processes in a society such as interests and initiatives, the role of the formal institutions (e.g. legislation and policy making), structural aspects, the impact of norms, values and ideas, and the distribution of power and wealth between different groups and individuals, and the processes that create, sustain and transform these relationships over time [66]. Subsequently, PEA situates the implementation strategies of family involvement in a broader understanding of the prevailing political and economic processes [67] and is useful to increase dialogue and reduce conflicts amongst stakeholders and to provide more effective policy and political programs on the targeted issue.

A document analysis will be performed on a sample of previous research, selected official publications and country-wide surveys from the period of about 2000–

2018 concerning the most important relevant historical and current policy development, legal framework, health economy aspects and educational programs and codes of ethics for key professions that might influence stakeholders' perceptions and affect the implementation of the national guidelines. The sample is based on a combination of desk research with search on relevant literature bases/websites, snowballing/reference nesting, and information from key experts.

Moreover, semi-structured focus group interviews with a purposive sample of key stakeholders from: a) politicians on a national level ($n = 1$), b) national health authorities (n = 1), c) national organisations dealing with complaint cases in mental health care (n = 1), d) professional associations and service user- /next-of-kin- organisations ($n = 3$), e) the regional health trust administration (n = 1), f) local health trust administration ($n = 2–3$) and g) political/administrative stakeholders from municipalities (n = 2–3), amounting to 11–15 interviews in total. We aim for larger focus groups with up to 10–15 participants, since this might give us a broader picture of considerations and contribute to display influencing power relations, interests and incentives through group interactions. However, the interview design will be flexible and adjusted to the preferences of informants (e.g. individual interviews) to ensure sufficient participation and information. Semi-structured interview guides, developed and adjusted to each stakeholder group, will address political/policy-making, legal and financial issues as described above, as well as interests, power relations and structural and cultural/ideological incentives regarding family involvement. Written consent will be obtained before the interviews, and the interviews will be recorded digitally and transcribed verbatim.

The main objective of the analysis is to identify barriers and facilitators on a political and institutional level that might be addressed to improve implementation of family involvement in CMHCs, by drawing on the analytic framework for PEA as developed by the Department for International Development (DFID) [64, 65]. The document analysis will make use of a combination of discourse analysis and content analysis, while the interviews will undergo a qualitative thematic content analysis [68–70]. The interview analysis and document analysis will be integrated with other data sources from the trial in the overall PEA, including future policy assessments before publication. Final choice of data analysis and assessments strategies will be decided upon after a closer consideration of the collected data material.

Data management and monitoring

All collected data will be stored in the University of Oslo's secure database (In Norwegian 'Tjenester for Sensitive Data' - TSD) and only project members will have access to the storage area. Questionnaires filled in online in the University's 'nettskjema'-application will be encrypted and stored directly in TSD. Questionnaires filled in on paper will be stored securely at the clinical units, before a project member transfers them to TSD. Personal data will always be stored separately from questionnaires, in the form of a code list/encryption key. A local research coordinator at each clinical unit will supervise local data collection and storage. The University of Oslo has signed individual contracts with each participating Health Trust, which specifies responsibilities for data collection and storage in accordance with Norwegian legislation. Since IFIP is a minimal risk trial, we do not have a data monitoring committee, but project members monitor the recruitment process and collection of outcomes closely to ensure conformity with the trial's ethical and methodological standards. Each study site has at least one designated project member to oversee and assist the implementation process (in the intervention arm) and data collection (in both arms).

Research ethics

The study will only include participants who are competent to make the decision to participate in research. We will obtain both oral and written consent and the participants can withdraw from the study at any time, without giving any reason and without experiencing any consequences for their treatment. Patients with psychotic disorders can be considered a particularly vulnerable group and we have made considerable efforts to make our research responsive to their needs, while also ensuring that they stand to benefit from the knowledge we may generate.

By using a cluster randomised design, the project needs to include more patients than would a study with individual randomisation, and it is therefore important that the choice of study design is justified. Consent to be exposed to our intervention is also sought at cluster level and not from patients and relatives within the cluster. Family involvement is a low-risk intervention and the local clinicians must assess whether it is contraindicated for certain patients and relatives. We also maintain that the treatment options in the intervention clusters will improve, and that we do not reduce the quality of the services offered in the control arm. After the implementation period, we will offer training and guidance to the control clusters as well.

In the political economy analysis we will interview political leaders and health administrators about issues which might be controversial. Therefore, confidentiality and possibilities for additional individual interviews will be underlined. The interviews will not gather information in terms of personal or political party nature, and the results will have to be published in a generalised way, without reference to their particular source.

All our procedures are in accordance with national and international standards for research ethics, including the Helsinki Declaration [71]. The study has been approved by the Norwegian regional committee for medical and health research ethics (REC) South East with registration number 2018/128. Important protocol modifications will be reported to REC, and the trial registry at clinicaltrials.gov will also be updated.

Discussion

The cluster randomised design of the IFIP trial will help us compare implementation-, service- and client outcomes between intervention and control arm. We will not compare the effectiveness of different implementation strategies or the effectiveness of different family interventions. Rather, we seek to combine recommended clinical interventions with recommended implementation interventions and compare the results of their systematic implementation with 'implementation as usual' [72]. We use the term 'implementation as usual' rather than 'treatment as usual' because the project will not prevent the control clusters from improving their family involvement practices, and there are considerable incentives for them to do so. The implementation of new clinical pathways in Norwegian mental health services coincides with the implementation period of our study. These clinical pathways set standards and deadlines for documentation, diagnostic evaluations and treatments, including family involvement practices, and will probably affect both intervention and control conditions. Since we measured baseline fidelity before the clinical pathways were launched, we might be able to monitor some of these effects.

Another challenge for our study is the timing of the inclusion of relatives and patients. To avoid selection bias, it would be optimal to include them prior to the randomisation of clusters. However since the implementation of complex practices requires time, we would risk that many patients would be discharged before being exposed to the intervention. By recruiting patients and relatives in the early- and mid-phases of the implementation period, they are likely to have various degrees of exposure to family involvement practices at inclusion. We hope to monitor parts of this exposure through the questionnaires.

Our trial may contribute to the paradigmatic change in mental health services towards working with relatives, building on the scientific evidence and moral arguments in favour of a family-oriented treatment approach. This study will employ a whole-ward strategy to implement family involvement for persons with psychotic disorders to make it an integrated part of every clinician's practice, rather than the domain of especially motivated personnel. Through our implementation support, we seek to alter both clinical practice and the structural and organisational conditions that may sustain this effort over time. This requires family involvement to be embedded in daily clinical activities, through routines, checklists and documentation [22]. At the same time, we recognise that many of the barriers to implementation represent genuine ethical dilemmas and conflicts of interests.

We also use a whole-ward research strategy, in the sense that we use broad inclusion criteria and do not require exposure to any specific intervention for our participants. In addition to the whole-ward strategy, our study has several characteristics that combined, to our knowledge, constitute a novel approach. We seek to implement a basic level of family involvement and support and family psychoeducation at the same time. Our study has a strong focus on sustainability and feasibility, where we encourage the clinical units to integrate some implementation interventions as part of their permanent structure. We employ responsive evaluation to ensure that both implementation and research is responsive to the needs of clinicians, patients and relatives. The IFIP trial includes patients and relatives in dyadic pairs and measures outcomes on multiple levels with both qualitative and quantitative methods. Finally, we also aim to see family involvement practices in a broader societal and public health context, by conducting a cost-effectiveness analysis and a political economy analysis. Our study may provide valuable knowledge to the fields of family involvement, mental health service research and implementation science.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12913-020-05792-4.

Additional file 1. The IFIP Intervention. Detailed description of the trial's intervention.

Abbreviations

ANOVA: Analysis of variance; BPB: Bedre psykosebehandling; CFIR: Consolidated Framework for Implementation Research; CMHC: Community Mental Health Centres; DFID: Department for International Development; DPS: Distriktspsykiatrisk Senter; FACT: Flexible Assertive Community Treatment; GLMM: Generalised linear mixed models; GOI: General organisational index; IFIP: Trial acronym: Implementation of Family Involvement for persons with Psychotic disorders; ICC: Intraclass correlation coefficient; ICER: Incremental cost-effectiveness ratio; ITT: Intention-to-treat; MRC: Medical Research Council; NEBP: National Evidence-Based Practices project; QALY: Quality adjusted life years; PEA: Political economy analysis; REC: Regional committee for medical and health research ethics; SD: Standard deviation; TSD: Tjenester for Sensitive Data

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Authors' contributions

RP, KSH, BW, TR, RN and EGML developed the original research protocol, which this article is based on, and thus made significant contributions to the conception and design of the study. LH, MR, RP, KSH, BW, KMH, IN, EA, RN and TR made substantial contributions to the further development of the intervention, study design and outcomes. LH continuously updated the research protocol in line with the project's developments and wrote the first draft of this article, with major contributions from MR and RP and also received contributions from KSH, TR, RN, IN, EA, and KMH. The authors critically revised the article, gave their final approval before submission, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

The study has been approved by the Norwegian regional committee for medical and health research ethics (REC) South East with registration number 2018/128. REC provides a general ethical approval to conduct the study as described in recruited clinical units. On the advice of local data protection officers at the trial sites, the PI on behalf of the University of Oslo has signed contracts on shared responsibility for data processing with each participating health care trust, allowing us to carry out the study at each trial site in accordance with the General Data Protection Regulation. Verbal and written informed consent to participate in the study will be obtained from all participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

Additional file 1 (Article 1)

The IFIP intervention

(The practices and structures marked with an asterisk (*) are recommended in the national guidelines and therefore intended to continue after the IFIP trial is finished).

1. Clinical interventions*

1.1 A basic level of family involvement and support

1.1.1 Basic assessment, structure and documentation

Clinicians should make sure:

- That relatives/next of kin are identified and documented. This includes documenting children, younger siblings and the extended network.
- That the patient is invited to a meeting dedicated to discuss family involvement, consent to family psychoeducation and other relevant issues. As a rule, this should take place before meetings with the relatives.
- That adult relatives are invited to a meeting dedicated to discuss family involvement, consent to family psychoeducation and other relevant issues. In general, this should take place without the patient.
- That relatives and the patient are invited to at least one meeting together with health care personnel.
- That the patient′s primary clinician attends at least one of the meetings with the patient and relatives together.
- That a crisis plan is developed, regularly updated and that relatives have contributed to, or at least been made familiar with, its contents.
- That family involvement, psychoeducation and the crisis plan are documented in the patient′s discharge report.

1.1.2 At least three meetings dedicated to family involvement and support

Meeting with the patient:

A meeting with the patient, without the relative(s) present, dedicated to discuss family involvement, consent to family psychoeducation, and other relevant issues. The meeting should be guided by a written checklist, documented in the patient records and cover the following items:

- Ask the patient directly: ′What is important for you to discuss with regards to family involvement?′ Then, make sure the conversation covers these topics.
- Ask the patient about his/her relationship to the relatives, including any children.
- Investigate whether the patient has experienced violence and/or abuse from the relatives.
- Talk to the patient about family involvement, confidentiality and conflicts of interest (how and why). Talk to the patient about his/her rights, and the different roles and responsibilities of patient, relatives and health care personnel. Make sure to elicit the patient′s concerns and preferences.
- Talk about issues connected to having younger children, their needs and parent responsibilities, if relevant.
- Systematically recruit patients with primary psychotic disorders to participate in psychoeducation in single-family groups. If the patient refuses, one should try to uncover why. If not contraindicated, one should ask again later, and consider this a continuous process. This applies to basic family involvement outside the psychoeducative model as well.

Meeting with the relative(s):

A meeting with the relative(s), usually without the patient, dedicated to discuss family involvement, consent to family psychoeducation, and other relevant issues. The meeting should be guided by a written checklist, documented in the patient records and cover the following items:

- Ask the relative directly: ′What is important for you to discuss with regards to family involvement?′ Then, make sure the conversation covers these topics.
- Talk to the relative about roles, responsibilities and regulations concerning family involvement, confidentiality and documentation.
- Ask how the relative experience his/her relationship to the patient. Listen to the relative′s concerns and receive his/her information about the patient.
- Identify the tasks, resources, carer burdens and strengths of the relative to assess his/her need for support, and give him/her advice on where to obtain it.
- Talk to the relative about common economic, social and health related issues connected with being a carer. Talk about strategies on how to handle these issues and where to obtain further support, if needed.
- Where relevant, talk about having younger children, about the parental role and responsibilities and what information and follow-up the children need, and have received.
- Investigate whether the relative(s) have experienced violence and/or abuse from the patient.
- Systematically recruit relatives of patients with primary psychotic disorders to participate in psychoeducation in single-family groups. If the relative refuses, one should try to uncover why. If not contraindicated, one should ask again later, and consider this a continuous process. This applies to basic family involvement outside the psychoeducative model as well.

Meeting together with health care personnel:

This might be a short introductory meeting, before the separate meetings, to agree on what issues can be discussed there. It might also be a longer meeting, to sum up what can be shared from the separate meetings. The separate and joint meetings might form the initial phase of family psychoeducation, or not, depending on the patient′s and the relative′s consent. In any case, the separate meetings should cover the items listed in the two previous sections.

1.1.3 Information to relatives and patients

The clinical unit should:

- Have written information about the unit′s family work available (how and why), and routinely distribute it to patients and relatives. It should also include information on relevant web resources and support groups.
- Have an overview of local units, organisations, agencies and people who could offer support within or outside the health services, and make sure this information reaches the relatives.
- Arrange seminars/information meetings for relatives on pertinent topics, at least two times a year.

1.2 Family psychoeducation in single-family groups

Family psychoeducation is a structured family intervention, based on the works of Falloon, Boyd and McGill (1) and Anderson, Reiss and Hogarty (2), and consists of the following elements:

- Initial sessions with the patient and relative(s), where the intervention is presented.
- Separate alliance sessions with patient and relative(s) with:
  - Mapping of warning signals.
  - Development of a crisis plan.
  - Mapping of the extended network of the patient.
  - Establishing goals for the treatment.
- Teaching sessions with the patient and relative(s) together. Should consist of the following themes:
  - Understanding and discussion of symptoms.
  - Cognitive difficulties and how they affect activities of daily living.
  - The stress/vulnerability model. Understanding and mapping of different stressors.
  - Coping strategies and family support.
- Communication skills and exercises.
- Problem-solving sessions. Practical and structured solving of problems related to the patient’s illness.
- If the patient or the relative(s) will not consent to participate in sessions together, the family workers should offer to perform separate sessions in line with the model.

2. Implementation interventions

2.1 Training and guidance of health care personnel*

2.1.1 Basic education and guidance on family involvement for patients with psychotic disorders

The clinical unit should provide yearly education to all clinical staff on:

- The importance of family involvement and the benefits of following the national guidelines.
- How to approach relatives in a good mannered way and recognise them through small gestures.
- The legal rights and roles of patients and relatives, and the health care services′ obligations towards them.
- How to promote family- and patient involvement during the treatment of primary psychotic disorders, with effective communication and cooperation through the various phases.
- Common challenges related to being a caregiver and where caregivers can obtain support, within or outside the health services. How to provide carers with the relevant information and adequate support.
- Professional, legal and ethical issues one may encounter during family involvement and strategies on how to handle these.

The health care personnel should have:

- Access to guidance in family involvement and support, e.g. from the family coordinator or personnel with expertise in family psychoeducation, from reflection groups or clinical ethics committees.

2.1.2 Training and guidance in family psychoeducation

- All clinical staff and leaders should be offered training and guidance in family psychoeducation sufficient to qualify as group leaders. In our project, certifying training is provided by The Early Intervention in Psychosis Advisory Unit for South East Norway, Oslo University Hospital Trust (TIPS Sør-Øst). It consists of a four-day course and follow-up guidance every sixth week for one year. All participants will be offered a one-day refresher course after one year. The training and guidance in family psychoeducation cover all the elements described in 2.1.1, with emphasis on theory and practical training in alliance sessions, psychoeducation, communication enhancement and problem solving.

2.2 A family coordinator*

- The clinical unit should appoint a designated professional, who receives training and regular guidance, to coordinate family involvement and support.

2.3 Other implementation measures

- The clinical units will constitute a local implementation team of 4-5 persons, working closely with the unit’s leader(s) to ensure management commitment and support. The team should include the family coordinator and other central clinicians, and establish systems to gain input and feedback from patients and relatives. The team supervises the local implementation process with assistance from project members.

- The project group will arrange a kick-off session at each intervention unit to provide information and build enthusiasm. It consists of a half-day seminar for all clinical staff, with introductions to family involvement and family psychoeducation, covering some of the elements in 2.1.1.
- The project group will conduct fidelity assessments every sixth month to assess the level of implementation of the intervention.
- The clinical units will receive systematic feedback with each fidelity report, and assistance in setting short- and long-term goals, distributing tasks and making work plans.
- The project group will arrange network meetings where the implementation team, family coordinators and leaders from different units can meet and share experiences, and receive further training.
- The project group will conduct focus group interviews and systematically use the resulting qualitative data to address local barriers, facilitators and ethical dilemmas, to meet objectives four and five. Based on qualitative interviews and other data sources, the project group will develop a comprehensive guide of barriers and ethical dilemmas, with particular emphasis on the potential strategies to overcome these.
- Regular quantitative evaluations of how patients and relatives experience their involvement and support in the clinical unit.*
- The clinical units will share useful tools, written material and examples on good practices with each other through a web page, and in the network meetings. The project group will provide conversation guides/checklists for discussing FI with patients and relatives. We will also provide an overview of important barriers to family involvement and strategies on how to handle them.
- The project group will offer the clinical units the possibility to assess clinicians′ readiness to implement a new practice through the Implementation Process Assessment Tool (IPAT) questionnaire (3). In the relevant units, a strategic sample of up to 15 clinicians will fill in the questionnaire, up to three times during the implementation period. The results will be summarised in a report to the unit′s leader(s), implementation team and clinicians, and can be used actively to guide the implementation process.

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II

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Family involvement practices for persons with psychotic disorders in community mental health centres – a cross-sectional fidelity-based study

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Abstract

Background: Family involvement for persons with psychotic disorders is supported by scientific evidence, as well as legal and ethical considerations, and recommended in clinical practice guidelines. This article reports a cross-sectional measurement of the level of implementation of such guidelines in fifteen community mental health centre units in Norway, and presents a novel fidelity scale to measure basic family involvement and support. The aim was to investigate current family involvement practices comprehensively, as a basis for targeted quality improvement.

Methods: We employed three fidelity scales, with 12–14 items, to measure family involvement practices. Items were scored from 1 to 5, where 1 equals no implementation and 5 equals full implementation. Data was analysed using descriptive statistics, a non-parametric test, and calculation of interrater reliability for the scales.

Results: The mean score was 2.33 on the fidelity scale measuring basic family involvement and support. Among patients with psychotic disorders, only 4% had received family psychoeducation. On the family psychoeducation fidelity assessment scale, measuring practice and content, the mean score was 2.78. Among the eight units who offered family psychoeducation, it was 4.34. On the general organizational index scale, measuring the organisation and implementation of family psychoeducation, the mean score was 1.78. Among the units who offered family psychoeducation, it was 2.46. As a measure of interrater reliability, the intra-class correlation coefficient was 0.99 for the basic family involvement and support scale, 0.93 for the family psychoeducation fidelity assessment scale and 0.96 for the general organizational index scale.

Conclusions: The implementation level of the national guidelines on family involvement for persons with psychotic disorders was generally poor. The quality of family psychoeducation was high, but few patients had received this evidence-based treatment. Our novel fidelity scale shows promising psychometric properties and may prove a useful tool to improve the quality of health services. There is a need to increase the implementation of family involvement practices in Norway, to reach a larger percentage of patients and relatives.

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Keywords: Family involvement, Psychotic disorders, Mental health services research, Schizophrenia, Family psychoeducation, Fidelity scale, Implementation science

Background

Family involvement practices in adult mental health services vary considerably, in terms of both quantity and quality. In this study, we focus on practices towards patients with psychotic disorders [1] and their relatives, but our methods and findings may be relevant to all health services dealing with severe and chronic illness.

Previous research describes how relatives of patients with severe mental illness report a lack of adequate information, support, and cooperation from mental health services [2, 3]. Studies have also documented the overall poor implementation of standardised family interventions in mental health care [4, 5], despite evidence of beneficial outcomes for both patients and relatives [6–15]. Family psychoeducation (FPE) is one such structured family intervention and a cornerstone of the evidence-based treatment of psychotic disorders. It begins with separate alliance sessions with patient and relative(s) and continues with joint psychoeducative sessions, communication skills exercises, and problem-solving sessions [16]. Mental health services may lack the capacity to offer such labour-intensive interventions to all of their eligible patients, and in a few cases the intervention is unnecessary or even contraindicated. Lack of resources, training and capacity are examples of organisational barriers to family involvement, but there are also significant clinical barriers, related to the perspectives of professionals, families, and patients [4, 17, 18].

However, clinicians should always attempt to establish a connection with the patient's relatives to assess their resources, burdens and needs as informal carers, and listen to their experiences, concerns and preferences. Relatives should be encouraged to provide information concerning the patient and should receive general information on the illness, the health services, and where to obtain further support if necessary. This basic level of family involvement and support is important in all cases of chronic and severe illness. In adult mental health services, it may be viewed as the obligatory basis of a pyramid that extends further to include family psychoeducation, consultation, and family therapy, depending on the families' needs [19].

In Norway, the Directorate of Health has provided general recommendations on family involvement and support in the health- and care services [20]. These are based on discussions between key stakeholders and experts, research evidence, and ethical considerations. They also include the legal regulations, whereby the health- and care services are obligated to provide information, guidance, support, and appropriate involvement to relatives, who have a corresponding right to these services. The Directorate has also issued specific guidelines on the treatment of psychotic disorders, recommending standardised family interventions as a first-line treatment during all phases of the illness [21], in line with comparable guidelines in other countries [22–25]. In this article, we refer to the general and specific guidelines on family involvement collectively as 'the national guidelines'.

To improve family involvement practices for persons with psychotic disorders, we needed a systematic and comprehensive assessment of the current level of implementation of these national guidelines. Our hypothesis was that the level of implementation would be low. As part of the 'Implementation of Family Involvement for persons with Psychotic disorders' – (IFIP) trial [26], we conducted a baseline assessment of family involvement practices in all fifteen participating community mental health centre (CMHC) units, using three fidelity scales. Measuring program fidelity is an established strategy in implementation science and mental health services research, providing a standardised assessment of evidence-based practices [27]. In order to investigate and implement basic family involvement and support, we developed a novel fidelity scale. The purpose of this article is both to present this new fidelity scale and to report the results from the baseline assessment. To our knowledge, this paper describes the first systematic, comprehensive and broad investigation of family involvement practices in CMHCs to date.

Methods

This article conforms to the 'Strengthening the reporting of observational studies in epidemiology (STROBE) statement' [28] (Additional file 1).

Study design, setting and participating sites

The investigation reported here is a cross-sectional substudy of the IFIP trial. The trial as a whole employs a cluster randomised controlled design, where a cluster is defined as one or more CMHC outpatient units with the main responsibility for treating patients with psychotic disorders in their discreet catchment area. We accepted all such units and invited all the sixteen CMHCs in five counties of the South-Eastern Norway Regional Health Authority to participate in the trial. Fifteen clinical sites

from twelve CMHCs agreed to participate, including both rural and urban units. The main reason given for non-participation among the remaining CMHCs was a lack of capacity to take part in a research project. Two of the participating sites were merged into one cluster, but were scored separately in this baseline assessment, which took place before randomisation. After randomisation, half of the clusters will receive training and support for 18 months to implement recommendations from the national guidelines, whereas the other half will be given training and support after the 18 months period. The sample size was calculated for the IFIP trial as a whole [26]. Table 1 sums up the characteristics of the clinical sites, and demonstrates the variation in organisation and structure among the services offered to patients with psychotic disorders in Norway.

Instruments

In the present survey, we employed three fidelity scales with 12–14 items. In each scale, the items are scored from 1 to 5, where 1 equals no implementation and 5 equals full implementation. The item scores are summed up and divided by the number of items in the respective scale, to produce an average score.

The BFIS scale

The project group developed a 14-item fidelity scale to measure the structure, content, penetration rate and implementation of Basic Family Involvement and Support (BFIS) (Additional file 2). The purpose of the scale is to operationalise the national recommendations on family involvement and support in the health- and care services. We were unable to find any similar fidelity scale in the published scientific literature.

The study protocol describes how the project group developed the IFIP intervention, by selecting recommendations from the national guidelines and clustering them into the following key elements [26]:

Clinical interventions:

1. A basic level of family involvement and support.

Table 1 Description of the 15 clinical sites (in sequence according to catchment area population)

Site	Catchment area population	Type of unit[a]	Full-time equivalent staff (FTE)	Total number of patients	Patients per FTE	Number of patients with psychotic disorders (F20–29)	Type of patients with F20–29[b]	Patients with F20–29 on community treatment order (CTO)
1	26.000	GPC, AOT	23.1	903	39.1	63	Early, Long-term	11 (17.5%)
2	29.000	AOT	6.3	112	17.8	30	Long-term	10 (33.3%)
3	29.000	AOT	7.5	85	11.3	28	Long-term	3 (10.7%)
4	36.000	DDT	9.8	188	19.2	57	Long-term	15 (26.3%)
5	45.000	AOT	1	28	28	28	Long-term	6 (21.4%)
6	58.000	GPC, AOT, POC	33.35	678	20.3	86	Early, Long-term	32 (37.2%)
7	63.000	AOT	12	175	14.6	100	Long-term	20 (20%)
8	66.000	AOT, POC	10	154	15.4	54	Early, Long-term	8 (14.8%)
9	111.000	POC	12	88	7.3	76	Early, Long-term	19 (25%)
10	118.000	AOT	12.1	186	15.4	148	Long-term	22 (14.9%)
11	130.000	POC	15.5	164	10.6	142	Early, Long-term	12 (8.5%)
12	135.000	POC	20	124	6.2	104	Early, Long-term	28 (26.9%)
13	140.000	POC	28	350	12.5	149	Early, Long-term	79 (53%)
14	150.000	POC	30	417	13.9	217	Early, Long-term	36 (16.5%)
15	175.000	POC	21	231	11	110	Early, Long-term	29 (26.4%)
Total	1.311.000	–	241.65	3883	–	1392	–	330 (23.7%)

[a] *AOT* Assertive outreach team, *DDT* Dual diagnosis team, *POC* Psychosis outpatient clinic, *GPC* General psychiatric clinic
[b] Early: Patients with newly diagnosed psychotic disorder. Long-term: Patients with chronic psychotic disorder

2. Family psychoeducation (FPE) in single-family groups.

Implementation interventions:

1. Training and guidance of health personnel.
2. A family coordinator.
3. Other implementation measures.

In parallel with that process, we identified model dimensions and items for the BFIS scale to cover the key elements of the IFIP intervention, apart from FPE (Table 2). A detailed account of the IFIP intervention is available in the study protocol [26].

While developing the BFIS scale, we sought to include items measuring both practice and penetration rate. By 'penetration rate', we mean the percentage of eligible patients and/or relatives that receive a certain invitation, treatment, service or practice. Consequently, the scale emphasises the importance of reaching a significant amount of patients and relatives, while also practicing the model accurately. Although the scale rates whether the unit provides annual training in basic family involvement and support (item 1), we did not require such training of the local clinicians in order for the unit to achieve scores on clinical practice items (items 3–13). In addition to clinical elements, the scale measures implementation elements to investigate the organisation and structure of family involvement practices. Thus, we intend the scale to give a comprehensive picture of the status quo, as well as being able to monitor changes during an implementation process.

The project group followed the standardised procedures for scale development described by Bond and colleagues [35]. One exception was that the scale had limited piloting because of time constraints. Some items were therefore eliminated or changed after the baseline data were collected. Where additional data and clarifications were required to adjust the scores, fidelity assessors did follow-up interviews with local personnel by phone. The baseline scores and reports were adjusted a second time after the fidelity assessments at 6 months follow-up, which resulted in some minor changes to the scale. Only the consensus scores were adjusted, in order not to interfere with the calculation of interrater reliability, except where eliminated items resulted in changes to the individual scores.

The FPE scale and the GOI scale

The 14-item Family Psychoeducation Fidelity Assessment (FPE) scale was used to measure the practice and content of FPE. This scale has demonstrated acceptable psychometric properties in previous trials, including in a Norwegian translation and context [36, 37]. The 12-item General Organizational Index (GOI) scale provided a complementary assessment of FPE's integration in the unit's practice, by measuring individualisation, quality improvement, program philosophy, and penetration rate. A recent study reported acceptable psychometric properties of the GOI scale, when used to assess the implementation of Illness Management and Recovery in Norway [38]. In both scales, an average score of 4 or above indicates adequate implementation, whereas scores below 4 signals low implementation. By convention, the sites that did not offer FPE to patients and their families were scored 1 on all items in the FPE scale and GOI. Item 7: 'prodromal signs' in the FPE scale was not scored, since the units in question treated patients with an established or tentative diagnosis of psychotic disorder, rather than prodromal or Ultra High Risk states.

Data collection

The clinical units were recruited during the three first quarters of 2018, and baseline assessments took place during November and December that same year. Trained fidelity assessors visited each unit and measured fidelity by performing structured interviews with leaders, clinicians and resource-persons, and by reviewing written material such as procedures, checklists, information leaflets, invitation letters, and didactic material. The head of the unit (department-, section- or team leader) was interviewed individually, whereas team leaders (if applicable), clinicians, and resource-persons (if applicable) were interviewed in separate or combined groups of 2–5 persons, with a total of 2–4 interviews of 1–1,5 h length at each site. We also collected organisational data (Table 1).

At each site, the two fidelity assessors first scored all items independently and then reached a consensus score for each item. The assessors, and the pairing of them, varied between sites. They were drawn from a pool of five researchers, who were also health professionals, but none of them worked at the clinical sites in the study. We exclusively assessed the units' practice towards patients with psychotic disorders and their relatives. The fidelity assessors prepared a detailed report for each site to accompany the scores. Scores and reports were sent to the units in the intervention arm after randomisation, for them to correct any misunderstandings or misconceptions, and to adjust scores if necessary. However, none of the units gave any feedback that resulted in a score adjustment. The sites in the control arm did not receive their scores or reports, to avoid influencing their practice during the intervention period.

Table 2 Key elements of the Basic Family Involvement and Support (BFIS) scale

Element	Recommendation/purpose	Items	Key references
Structural/ implementation measures	*The unit should:*		
Training and supervision of health personnel	Provide all clinicians with basic competence and skills, to ensure that family involvement becomes one of the cornerstones of treatment, rather than optional or random.	1	[20, 29]
Family coordinator – General structure and responsibilities	Appoint a family coordinator to help implement and sustain the practice. Relevant tasks may include writing and/or updating written material, arranging information courses for relatives, providing tools, internal training and supervision to local personnel, overseeing implementation efforts and being part of the implementation team.	2	[20]
Implementation measures	Establish an implementation team to organise and supervise the implementation process, and ensure management commitment.	14	[29]
Routines/procedural measures			
Identification and documentation of the relatives	Ensure that personnel identify and document the relatives. This is fundamental to establish any kind of family involvement. The scale rates only the penetration rate of identifying and documenting the next of kin and children, but it is also helpful to identify other important persons and the extended network.	5	[20]
Documentation of family involvement in the patient's discharge report	Ensure that clinicians document family involvement in the patient's discharge report, so that other clinicians in specialist health services or municipalities, who will care for the patient, get an overview of the family involvement conducted so far to establish a continuity of care.	13	[20, 30, 31]
Clinical measures			
Conversation(s) with the patient focusing on family involvement	Offer patients with psychotic disorders at least one consultation/conversation, where the major part is dedicated to discuss family involvement and FPE. A way to standardise the content of such conversations is to employ a checklist, with necessary adjustments to the patient's specific needs.	3,6,7	[6, 20, 21]
Conversation(s) with the relative(s) focusing on family involvement	Offer relatives at least one conversation without the patient present. This provides them with an opportunity to express how the patient's illness affect their lives, without fearing how this information might affect the patient. These conversations are modelled after the 'alliance sessions' in the FPE-model and can be standardised by using a checklist.	4,8	[16, 19, 20]
Conversation(s) with the patient and relative(s) together focusing on family involvement	Offer the patient and relative(s) a conversation together. This could be an introductory conversation to agree on some rules for the separate conversations, or it could be after the separate conversations to sum up the things that can be shared. The conversation might also constitute the initial phase of FPE. The patient's primary clinician should attend at least one such conversation to assure the integration between family involvement and other treatment strategies.	9,10	[16, 20]
Developing a crisis/coping plan	Ensure that a crisis/coping plan is made, ideally when the patient is competent and/or in a stable phase of the illness. It should be regularly updated and include the patient's preferences if the illness worsens, and relevant contacts. Relatives may contribute to, or should at least be made familiar with, its contents.	11	[21, 32–34]
Information meetings/ psychoeducative seminars for relatives	Offer relatives information meetings/psychoeducative seminars. This is particularly important for relatives of patients who refuse to participate in FPE, or refuse any contact between health professionals and relative(s).	12	[11, 20]

Data analysis

We examined item distributions for all three scales, including means, ranges, standard deviations and number of sites achieving low, adequate and full implementation of the various items. Based on organisational data from the clinical sites, we calculated the percentage of patients with psychotic disorders who had received FPE.

For the BFIS scale, we calculated the percentage of exact agreement for each item. We also investigated interrater reliability (IRR) by calculating the Intra-class Correlation Coefficient (ICC) for total mean fidelity and for each item, using a one-way random effects analysis of variance model for agreement between two assessors. By employing the same model, we calculated the ICC for the FPE scale and the GOI scale. To investigate a possible correlation, between whether the units offered FPE and the BFIS scale scores, we employed an independent samples Mann-Whitney U test. All data analyses were carried out using SPSS version 26.

Results

Basic family involvement and support

Item distributions and interrater reliability for the BFIS scale are listed in Table 3. The mean BFIS score in fifteen sites was 2.33, ranging from 1.57 to 3.79. None of the sites had annual training of their health professionals in family involvement and support. Personnel had access to supervision on the subject in eleven of the sites (item 1). Only four sites had health professionals designated to coordinate family involvement and support (item 2). Their responsibilities varied and one of them did not have allocated time to the task. In accordance with the law, all units had procedures and health personnel responsible for taking care of children as next of kin.

Overall, the units routinely identified the patients' next of kin and discussed family involvement with most of the patients (items 5 and 7). None of the units had routines to provide written information to patients and relatives about useful websites, support groups and resources, and only one site routinely provided written information about their unit's family involvement (item 2). Five units offered information meetings/ psychoeducative seminars for relatives, but the recruitment strategies to, and attendance of, these courses varied between the units (item 12).

There was a large variation in practices between the units when it came to inviting patients and relatives to a conversation with personnel, together and/or separately, to discuss family involvement (items 6, 8, 9 and 10). Only two of the units used checklists to standardise the content of such conversations, and the topics usually covered varied between clinicians and between sites (items 3 and 4). The use of crisis/coping plans (item 11) and documentation of family involvement in the patients' discharge report (item 13) also varied considerably.

There were small differences in average scores on several items, between the units who offered FPE and those who did not. To investigate any correlation between the BFIS scores and the units' FPE status, we employed an independent samples Mann-Whitney U Test with two-tailed significance level $\alpha = 0.05$. For the average BFIS scores we calculated $U = 27.5$ and $p = 0.955$. *P*-values for individual items varied greatly, from $p = 1.0$ (items 1, 3, 5 and 14) to $p = 0.054$ (item 13). Thus, no statistically significant correlation was found.

Family psychoeducation

Eight of fifteen sites offered FPE to patients with psychotic disorders and their relatives. The percentage of patients with psychotic disorders who had received or were receiving FPE in all units was 4.2%, ranging from 0 to 17.5% between sites. In the sites that offered FPE, the percentage was 9.4%, ranging from 1.9 to 17.5%. One

Table 3 Item distributions and interrater reliability for the Basic Family Involvement and Support (BFIS) scale ($n = 15$)

Item	Description	Mean (SD)	Number of sites achieving score			Agreement (%)	ICC
			1–3	4	5		
	Structure, content and implementation subscale						
1	Training and supervision of health personnel	1.00 (0.00)	15	0	0	100	1.000
2	Family coordinator	1.53 (0.99)	14	1	0	87	0.924
3	Conversation(s) with the patient	2.47 (0.64)	14	1	0	80	0.858
4	Conversation(s) with the relative(s)	2.40 (0.91)	14	0	1	60	0.917
14	Implementation measures	1.00 (0.00)	15	0	0	100	1.000
	Subscale total	1.68 (0.43)	15	0	0	–	0.931
	Penetration rate subscale						
5	Identifying/ documenting the relatives	5.00 (0.00)	0	0	15	100	1.000
6	Conversation(s) with the patient	1.27 (1.03)	14	0	1	100	1.000
7	Discussing family involvement	4.13 (0.83)	4	5	6	73	0.904
8	Conversation(s) with the relative(s)	1.60 (0.83)	14	1	0	80	0.940
9	Conversation(s) with the patient and relative(s)	2.73 (1.22)	11	3	1	73	0.952
10	Primary clinician attends one meeting	2.60 (1.06)	12	3	0	87	0.969
11	Crisis/coping plan	3.20 (0.94)	8	7	0	80	0.962
12	Seminars/meetings for relatives	1.67 (1.23)	13	1	1	100	1.000
13	Family involvement in discharge report	2.00 (1.20)	12	3	0	80	0.910
	Subscale total	2.69 (0.55)	14	1	0	–	0.979
	Scale total	2.33 (0.47)	15	0	0	–	0.991

unit offered both FPE and another family intervention inspired by Open Dialogue [39], but the remaining seven did not provide such interventions to their patients at all.

Item distributions for the FPE and GOI scales are listed in Tables 4 and 5. The mean fidelity score on the FPE scale was 2.78, ranging from 1.00 to 4.77. However, the distribution was markedly bimodal, since the seven units who did not offer FPE were scored 1 on all items. In the eight sites that did offer FPE, the mean score was 4.34, ranging from 4.00 to 4.77, showing that all of them practiced the model with adequate fidelity. Only four sites had appointed personnel to coordinate FPE activities (item 1). In general, clinicians remained true to the structure and content of the model (items 2–6, 8, 9 and 11–13), but the use of multimedia sources varied (item 10). Active recruitment of patients and relatives to FPE was generally low, with an average fidelity score of 2.5 in the sites that offered FPE (item 14).

A similar tendency was seen in the GOI scores, where only one unit had a standardised form of eligibility identification (item 2) and none of them had provided FPE to more than 20% of eligible patients (item 3). Our premise when rating item 3 was that all patients with psychotic disorders were eligible to receive FPE, which is probably an overestimate. The average GOI score in all 15 sites was 1.78, ranging from 1.00 to 3.00. Among the eight sites who had implemented FPE, the average GOI score was 2.46, ranging from 1.92 to 3.00, indicating that none of these had achieved an adequate integration of FPE in their organisation.

Psychometric properties

From the present survey in 15 sites, we have calculated the percentage of exact agreement and the intra-cluster correlation coefficient (ICC) for each item, and the mean total fidelity of the BFIS scale (Table 3). These preliminary measures of IRR indicate a high level of agreement between raters, with an ICC of 0.99 for mean total fidelity.

Concerning the FPE scale, we calculated an ICC of 0.93 for mean total fidelity, whereas the GOI scale had an ICC of 0.96. Both numbers suggest a high level of agreement between raters. These calculations were only based on the results from the eight sites that offered FPE, because including the unanimous scores from the units who did not offer FPE would produce an artificially high correlation.

Discussion

Basic family involvement and support

The results from this study demonstrate a general lack of structures and standard procedures in Norwegian CMHCs, when it comes to family involvement and support for persons with psychotic disorders.

Several units had local resource persons with special competence in family involvement, who worked hard to increase the awareness and recognition of their field. During this survey, the project group took note of many exemplary practices that could inspire other units and clinicians in the subsequent phases of the IFIP trial. Some of the clinical sites had established local structures and routines for basic family involvement and support,

Table 4 Item distributions for the Family Psychoeducation fidelity assessment (FPE) scale

		All units ($n = 15$)				Units with FPE ($n = 8$)			
		Mean (SD)	FPE item ratings by site			Mean (SD)	FPE item ratings by site		
Item	Description		Low	Adequate	Full		Low	Adequate	Full
1	Family intervention coordinator	1.60 (1.18)	14	0	1	2.13 (1.46)	7	0	1
2	Session frequency	3.00 (1.96)	7	2	6	4.75 (0.46)	0	2	6
3	Long-term FPE	3.13 (2.07)	7	0	8	5.00 (0.00)	0	0	8
4	Quality of clinician-family alliance	2.93 (1.91)	7	3	5	4.63 (0.52)	0	3	5
5	Detailed family reaction	3.13 (2.07)	7	0	8	5.00 (0.00)	0	0	8
6	Precipitating factors	3.13 (2.07)	7	0	8	5.00 (0.00)	0	0	8
7	Prodromal signs (not rated)	–	–	–	–	–	–	–	–
8	Coping strategies	3.13 (2.07)	7	0	8	5.00 (0.00)	0	0	8
9	Educational curriculum	2.93 (1.94)	8	1	6	4.63 (0.74)	1	1	6
10	Multimedia education	2.13 (1.64)	12	0	3	3.13 (1.73)	5	0	3
11	Structured group sessions	3.13 (2.07)	7	0	8	5.00 (0.00)	0	0	8
12	Structured problem solving	3.13 (2.07)	7	0	8	5.00 (0.00)	0	0	8
13	Stage-wise provision of services	2.93 (1.94)	8	1	6	4.63 (0.74)	1	1	6
14	Assertive engagement and outreach	1.80 (0.86)	15	0	0	2.50 (0.54)	8	0	0
	Scale total	2.78 (1.74)	7	8	0	4.34 (0.30)	0	8	0

Table 5 Item distributions for the General Organizational Index (GOI) scale

		All units ($n = 15$)				Units with FPE ($n = 8$)			
		Mean (SD)	GOI item ratings by site			Mean (SD)	GOI item ratings by site		
Item	Description		Low	Adequate	Full		Low	Adequate	Full
	Individualisation								
2	Eligibility/client identification	1.27 (1.03)	14	0	1	1.50 (1.41)	7	0	1
4	Assessment	2.53 (1.69)	10	2	3	3.87 (1.13)	3	2	3
5	Individualised treatment plan	1.73 (0.88)	15	0	0	2.38 (0.74)	8	0	0
6	Individualised treatment	2.93 (2.02)	8	0	7	4.63 (1.06)	1	0	7
12	Client choice regarding services	2.87 (1.85)	7	4	4	4.5 (0.54)	0	4	4
	Quality improvement								
7	Training	1.53 (1.41)	13	0	2	2.00 (1.85)	6	0	2
8	Supervision	1.87 (0.99)	14	1	0	2.62 (0.74)	7	1	0
9	Process monitoring	1.00 (0.00)	15	0	0	1.00 (0.00)	8	0	0
10	Outcome monitoring	1.00 (0.00)	15	0	0	1.00 (0.00)	8	0	0
11	Quality assurance	1.00 (0.00)	15	0	0	1.00 (0.00)	8	0	0
	Additional items								
1	Program philosophy	2.60 (1.64)	9	4	2	4.0 (0.76)	2	4	2
3	Penetration	1.00 (0.00)	15	0	0	1.00 (0.00)	8	0	0
	Scale total	1.78 (0.81)	15	0	0	2.46 (0.42)	8	0	0

and several had information meetings or other support measures for relatives.

In most units however, contact with and involvement of relatives appeared both random and inadequate, depending highly on the practice of the patient's clinician. As such, the results of this systematic survey of mental health services is consistent with the findings of previous research on relatives' experiences [2, 3]. The poor organisation of family involvement and support for adult relatives contrasted distinctly with the legally mandated structures, procedures and responsibilities for children as next of kin. Nearly all the units in our survey had personnel responsible for taking care of children as next of kin and written procedures on this subject, which were widely used among the remaining personnel. The legislation concerning children as next of kin was passed in 2009, whereas the guidelines on family involvement in the health- and care services were published in 2017. The differences in implementation rates may be primarily due to legal incentives (and sanctions) being more important to administrators than following guidelines, but also related to the longer time span and family work towards children receiving more attention. In any case, it shows that improvement in CMHCs' family work is feasible with appropriate focus, support, and incentives.

Several clinicians had frequent contact with relatives by phone, and the BFIS scale does not include the penetration rate of such calls. The low percentage of relatives who were invited to a conversation at the CMHC, with or without the patient present, indicate that such conversations are not part of the standard approach in most units. The variable use of crisis plans and infrequent documentation of family involvement in the patients' discharge reports may disrupt the continuity of care that is vital to this patient group and their next of kin.

The fact that none of the units had annual training of their clinical personnel in family involvement is a particularly important finding, since the education of health professionals in Norway have generally given limited attention to this subject. It therefore requires substantial effort within the health services to implement family involvement as a standard approach among clinicians.

There may be several reasons why family involvement has received such little attention, in both training and implementation in Norwegian mental healthcare. The research literature suggest that poor implementation is a problem internationally, and that barriers to family involvement exist on multiple levels. On a system level, these include a lack of financial incentives and explicit prioritization from managers and politicians, organisational cultures and paradigms, attitudes of leaders and staff towards evidence-based practices in general and/or family involvement in particular, inter-professional struggles, and poor access to training and supervision [4, 17, 18]. As part of the IFIP trial, we aim to investigate barriers to and facilitators for family involvement practices on a clinical, organisational and political level in the Norwegian context, trough qualitative methods.

The BFIS scale

The present model for basic family involvement and support is novel and has not yet been investigated scientifically as a whole. It consists of elements whose rationale varies from scientific evidence to legal frameworks and rights, as well as moral obligations. This reflects the composite nature of the guidelines that the model is based on. As such, the BFIS fidelity scale is one of the first instruments of its kind to measure the implementation of guidelines and practices that are not exclusively evidence-based. We would argue that this new application of the fidelity methodology is justified, since many practices within mental health services are based on predominantly ethical and/or legal considerations, rather than expectations of treatment effect. The scale should also be appropriate to measure basic family involvement and support for patients with other forms of severe mental illness. Perhaps, with some modifications, it may be suitable for health services towards other patient groups with chronic and severe illness.

Concerning psychometric properties, the scale shows promising IRR, appears to have relevant content and captures variability in practice, but we cannot yet establish its benchmark value. The percentage of exact agreement for each item was generally high, but the lack of standard procedures and high variability among practitioners complicated the scoring of some items. The fact that units who offered FPE did not score significantly better or worse on the BFIS scale, indicates that the scale measures practices that are independent of FPE, which may support the introduction of the scale. The Mann-Whitney U test was appropriate, because of the low sample size and the irregular distribution of the data. However, given the low sample size and generally low power of non-parametric tests, this lack of significant correlation should be interpreted with caution.

Family psychoeducation

The Norwegian guidelines recommending structured family interventions as a first-line treatment for persons with psychotic disorders were published in 2013, and the evidence supporting such interventions has been available for much longer. Yet, only 4.2% of the patients with psychotic disorders in our participating units had received FPE, and nearly half of the sites did not offer FPE or any family intervention at all. These findings are consistent with the international research literature [4, 5].

In the units who did provide FPE, the penetration rate was low and the majority of sites lacked structures and procedures to identify and recruit eligible patients, and to coordinate FPE activities. However, the quality of the FPE provided was consistently high, suggesting that the training and supervision the units had received from The Early Intervention in Psychosis Advisory Unit for South East Norway (TIPS Sør-Øst) was excellent. Yet, training and guidance in FPE by itself did not appear sufficient to implement the intervention as an integrated part of the unit's organisation and practice. This is revealed by the poor GOI scores, which illustrate the benefits of using scales that not only measure practice and content, but also organisation, implementation and individualisation [38]. The BFIS scale is an attempt to combine these elements in a single instrument.

Strengths and limitations

One advantage of fidelity measurements is the standardised and structured assessment of all units in a sample [27]. A weakness of this approach is that one does not investigate practices that are not addressed by the instruments. However, in our fidelity reports we recorded if the units had any family involvement practices that our instruments failed to credit, and these were few.

We could have included additional data sources, such as observations of FPE-sessions and interviews with patients and relatives. A review of randomly chosen patient records at each site would have strengthened the validity of our survey, particularly of the penetration rate items. Unfortunately, gaining access to the patient record software proved so legally complicated that this endeavour had to be abandoned.

When it comes to the representability of the sample, we only included units from the southeast of Norway and we exclusively measured their practice towards patients with psychotic disorders and their relatives. In terms of external validity, these findings do not necessarily reflect the situation in other regions of the country and/or practice towards other patient groups. Yet, the sample of clinical units in our investigation include both urban and rural sites and serves approximately 25% percent of the Norwegian population. Consequently, our survey measures specialist health services towards a large part of this patient group and their relatives in Norway. We have little reason to believe that the clinical units' family involvement practices towards other patient groups with severe mental illness were more systematic or of higher quality.

The recruitment of clinical units, both in terms of sample size and type of units, was made considering the trial as whole, and not specifically this cross-sectional sub-study. It could be argued that units who did not offer FPE had greater incentives to join our research project, which could lead to a form of selection bias. However, most of the CMHCs in the region agreed to participate, and the ratio of units who offered FPE versus those who did not was the same among participant and non-participant CMHCs.

Conclusions

This cross-sectional assessment confirmed our hypothesis; that the uptake of the national guidelines on family involvement for persons with psychotic disorders in Norwegian CMHCs was generally poor. Few patients and relatives had received FPE, which is a key ingredient in the evidence-based treatment for these patients. However, the quality of FPE was consistently high, when provided. Our novel fidelity scale, which measures basic family involvement and support, shows promising preliminary psychometric properties and may prove a useful tool to improve the quality of health services. There is a need to increase the implementation and penetration rate of family involvement practices for patients with psychotic disorders and their relatives in Norway.

Abbreviations

AOT: Assertive outreach team; BFIS: Basic family involvement and support; CMHC: Community mental health centre; CTO: Community treatment order; DDT: Dual diagnosis team; FPE: Family psychoeducation; FTE: Full-time equivalent staff; GOI: General organizational index; GPC: General psychiatric clinic; ICC: Intra-class correlation coefficient; IFIP: Implementation of family involvement for persons with psychotic disorders; IRR: Interrater reliability; POC: Psychosis outpatient clinic; STROBE: Strengthening the reporting of observational studies in epidemiology

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12888-021-03300-4.

Additional file 1. STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies.

Additional file 2. Fidelity scale for Basic Family Involvement and Support (BFIS).

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Authors' contributions

All authors made significant contributions to the conception and design of the study, with particularly substantial contributions from KSH, TR and RP. LH and KSH developed the BFIS fidelity scale with input from the other authors. MR did a preliminary mapping of the participating units' structure, organisation and practice, and made substantial efforts to recruit clinical units with aid from the other authors. KSH provided training in fidelity measurement to the fidelity assessors. MR, LH and KMH did most of the data collection, with help from RP and KSH. LH performed the data analysis with input from TR and MR. LH wrote the first draft of this article, with major contributions from MR and KSH and also received contributions from TR, KMH and RP. All the authors critically revised the article, gave their final approval before submission, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study has been approved by the Norwegian regional committee for medical and health research ethics (REC) South East with registration number 2018/128. REC provides a general ethical approval to conduct the study as described in recruited clinical units. On the advice of local data protection officers at the trial sites, the PI on behalf of the University of Oslo has signed contracts on shared responsibility for data processing with each participating health care trust, allowing us to carry out the study at each trial site in accordance with the General Data Protection Regulation. In the study reported here, informed consent was obtained orally from all the interview participants. No personal data or information was collected from the participants and no transcripts or recordings were made of the interviews. Fidelity scores and reports were the only data produced. All the methods reported here were performed in accordance with the ethics committee approval, national legal regulations and guidelines for research ethics, and the WMA declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

III

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ORIGINAL ARTICLE

Implementation of Guidelines on Family Involvement for Persons with Psychotic Disorders (IFIP): A Cluster Randomised Controlled Trial

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Abstract

Family involvement is part of the evidence-based treatment for persons with psychotic disorders, yet is under-implemented despite guideline recommendations. This study assessed whether an implementation support programme increased the adherence to guidelines on family involvement, compared to guideline/manual only. In a cluster randomised design, community mental health centre units in South-East Norway went through stratified allocation to the experimental (n = 7) or control (n = 7) arm. Experimental clusters received an implementation support programme including clinical training and supervision, appointing a family coordinator and an implementation team, a toolkit, and fidelity measurements at baseline, 12, 18, and 24 months with on-site feedback and supervision. Control clusters received no such support and had fidelity measurements at baseline and 24 months without feedback. During fidelity measurements, adherence to the guidelines was measured with the basic family involvement and support scale, the general organizational index, and the family psychoeducation fidelity scale, the latter being the primary outcome. The scales consist of 12–14 items rated from 1 to 5. Data was analysed with an independent samples t-test, linear mixed models, and a tobit regression model. At 24 months, the mean scores were 4.00 or higher on all scales in the experimental arm, and the increase in adherence to the guidelines was significantly greater than in the control arm with p-values < 0.001. Large-scale implementation of guidelines on family involvement for persons with psychotic disorders in community mental health centres may be accomplished, with substantial implementation support.

Trial Registration: ClinicalTrials.gov Identifier NCT03869177. Registered 11.03.19.

Keywords Psychotic disorders · Family involvement · Family psychoeducation · Fidelity scale · Guideline implementation · Mental health services

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Introduction

Family involvement is a key element of the evidence-based treatment for persons with psychotic disorders (F20–29 in ICD-10). Its fundamental role is supported by well-documented beneficial effects for patients and relatives (Bighelli et al., 2021; Bird et al., 2010; Claxton et al., 2017; Hasan & Jaber, 2019; Lobban et al., 2013; Ma et al., 2018; Pharoah et al., 2010; Pilling et al., 2002; Pitschel-Walz et al., 2001; Rodolico et al., 2022; Sin et al., 2017; Yesufu-Udechuku et al., 2015), but also rests on firm moral and legal foundations.

Family psychoeducation (FPE) is a structured family intervention that includes separate alliance sessions with patient and relative(s) followed by joint psychoeducative sessions, communication skills exercises, and problem solving sessions (Lucksted et al., 2012). Based on a synthesis of the scientific literature, clinical practice guidelines worldwide recommend such family interventions as a first-line treatment during all stages of psychotic disorders (Dixon et al., 2010; Galletly et al., 2016; Gühne et al., 2015; Kuipers et al., 2014). Even so, the implementation of family interventions in mental health services appears generally poor and unsystematic, with few patients and relatives receiving such interventions (Bucci et al., 2016; Hestmark et al., 2021; Rummel-Kluge et al., 2006). Studies also indicate that even the most basic forms of family involvement, cooperation, and support are offered irregularly (Hestmark et al., 2021; Vermeulen et al., 2015; Weimand et al., 2011). This highlights the need for implementation research with a focus on both basic and advanced levels of family involvement.

Family interventions are not the only evidence-based practices (EBPs) that suffer from underuse in mental health care (Torrey et al., 2001). General barriers that hinder the adoption of EBPs or clinical practice guidelines in the health services include a lack of leadership commitment and prioritisation, conflicting professional views, lack of resources, structure, training, and supervision (Bucci et al., 2016). Yet, the implementation of family involvement practices in mental health care faces additional and particular obstacles of a clinical, ethical, cultural, and historical nature. Examples include biomedical paradigms where family involvement is not considered treatment, historical paradigms where relatives are considered a significant cause of the illness, and ethical dilemmas concerning patient autonomy and the duty of confidentiality (Eassom et al., 2014; Landeweer et al., 2017; Szmukler & Bloch, 1997). Thus, a systematic effort to implement family involvement in mental health services should include strategies to address both general and particular barriers.

Implementation strategies frequently used in mental health services research include training and supervision, toolkits and educational material, local or regional support teams, and some form of quality or fidelity monitoring (Menear & Briand, 2014). Fidelity is a central implementation outcome, assessing whether the intervention was delivered and implemented as prescribed (Proctor et al., 2011). The rationale is that the implementation of core elements of EBPs, previously tested through rigorous research designs, will generate similar outcomes. Fidelity measurements may also enable researchers to distinguish between failure of the intervention and failure of implementation (Bond & Drake, 2020). Previous fidelity-based studies on the implementation of FPE have been either experimental non-randomised trials (Kealey et al., 2015; McHugo et al., 2007), or unable to demonstrate significant increases in fidelity (Ruud et al., 2021).

In 2017, the Norwegian Directorate of Health issued national recommendations on family involvement and support in the health- and care services, based on legal regulations, research evidence, ethical considerations, and discussions between key stakeholders and experts (Norwegian Directorate of Health, 2017). These general recommendations supplement the clinical practice guidelines that concern family interventions specifically in the treatment of psychotic disorders (Norwegian Directorate of Health, 2013). We refer to the general and specific guidelines collectively as 'the national guidelines'. The results from a systematic baseline survey, of family involvement practices in participating clinical sites, suggest that the level of implementation of these guidelines in Norwegian community mental health centres (CMHCs) was generally low (Hestmark et al., 2021).

The purpose of the 'Implementation of Family Involvement for persons with Psychotic disorders' (IFIP) trial was to implement selected recommendations from the national guidelines in Norwegian CMHCs (Hestmark et al., 2020). With a comprehensive Implementation Support Programme (ISP), the project sought to implement a combination of basic and advanced levels of family involvement, using both general and specific implementation strategies to address barriers on multiple levels. The aim of this article is to answer the following research question: Did the IFIP ISP lead to an increased adherence to the national guidelines, compared to guideline/manual only?

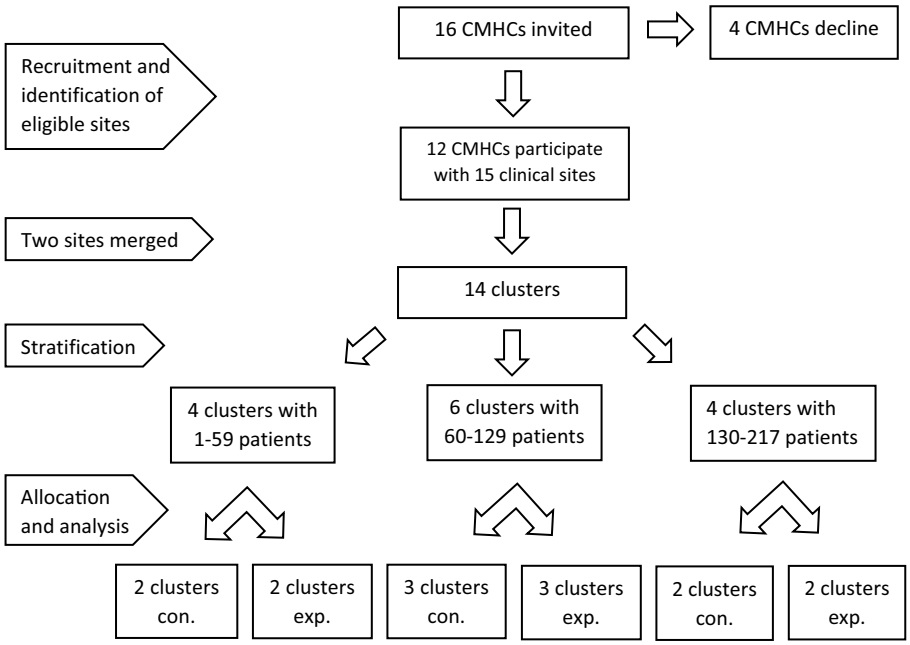

Fig. 1 Flow diagram of the recruitment, stratification, allocation, and analysis of clusters in the IFIP trial. *CMHC* Community mental health centre, *Con* control, *Exp* experimental

Methods

This article conforms to the 'Consolidated Standards of Reporting Trials (CONSORT) statement 2010: extension to cluster randomised trials' (Campbell et al., 2012) (Supplementary file 1).

Trial Design, Sample Size, and Participating Clinical Sites

The IFIP trial employed a cluster randomised controlled design. A cluster was defined as one or more CMHC outpatient units that had the main responsibility for long-term treatment of patients with psychotic disorders in a discrete catchment area. There were no further eligibility criteria for clusters. The design was appropriate to analyse differences in implementation outcomes between experimental and control conditions, but also critical to avoid contamination in the sub study on patients' and relatives' outcomes (Hestmark et al., 2020).

Adherence to the national guidelines was assessed through fidelity measurements. The unit of analysis was the cluster, and fidelity outcomes pertain to the cluster level. When calculating the sample size, we assumed a mean difference in fidelity scores of 1.82 with a standard deviation of 0.80, after 18 months of implementation support. These numbers were based on the results from two previous implementation studies using the family psychoeducation fidelity assessment (FPE) scale (Kealey et al., 2015; McHugo et al., 2007), which therefore must be regarded as the primary outcome, although the remaining scales are of equal importance. For a two-sided Independent samples t-test, with 5% significance level and 80% power, we estimated that four clusters in each arm were required to show that implementation support leads to a significant increase in adherence. Since the IFIP trial also assessed outcomes for patients and relatives, it required seven clusters in each arm to secure adequate power, taking the number of potential participants and the cluster effect into account (Hestmark et al., 2020).

All the 16 CMHCs in five counties of the South-Eastern Norway Regional Health Authority were invited to participate in the trial, and 15 clinical sites from 12 CMHCs in 6 health trusts agreed to participate during summer/fall 2018. These 12 CMHCs together serve approximately 25% of the Norwegian population. Among the remaining CMHCs, the principal reason given for non-participation was a lack of capacity to take part in a research project. The participating clinical sites included various adult service types, such as assertive outreach teams, early intervention units, dual diagnosis teams, as well as mixed or specialised outpatient clinics. Their clients were 18 years or above, and included both patients with recently diagnosed and chronic psychotic disorders. A detailed account of the participating clinical sites and their baseline fidelity scores has been published (Hestmark et al., 2021). Each site corresponds to one cluster, except for two collaborating sites that were merged to get an even number of clusters for randomisation. There was no drop-out of clusters during the trial, neither from the intervention in the experimental arm, nor from analysis in either arm.

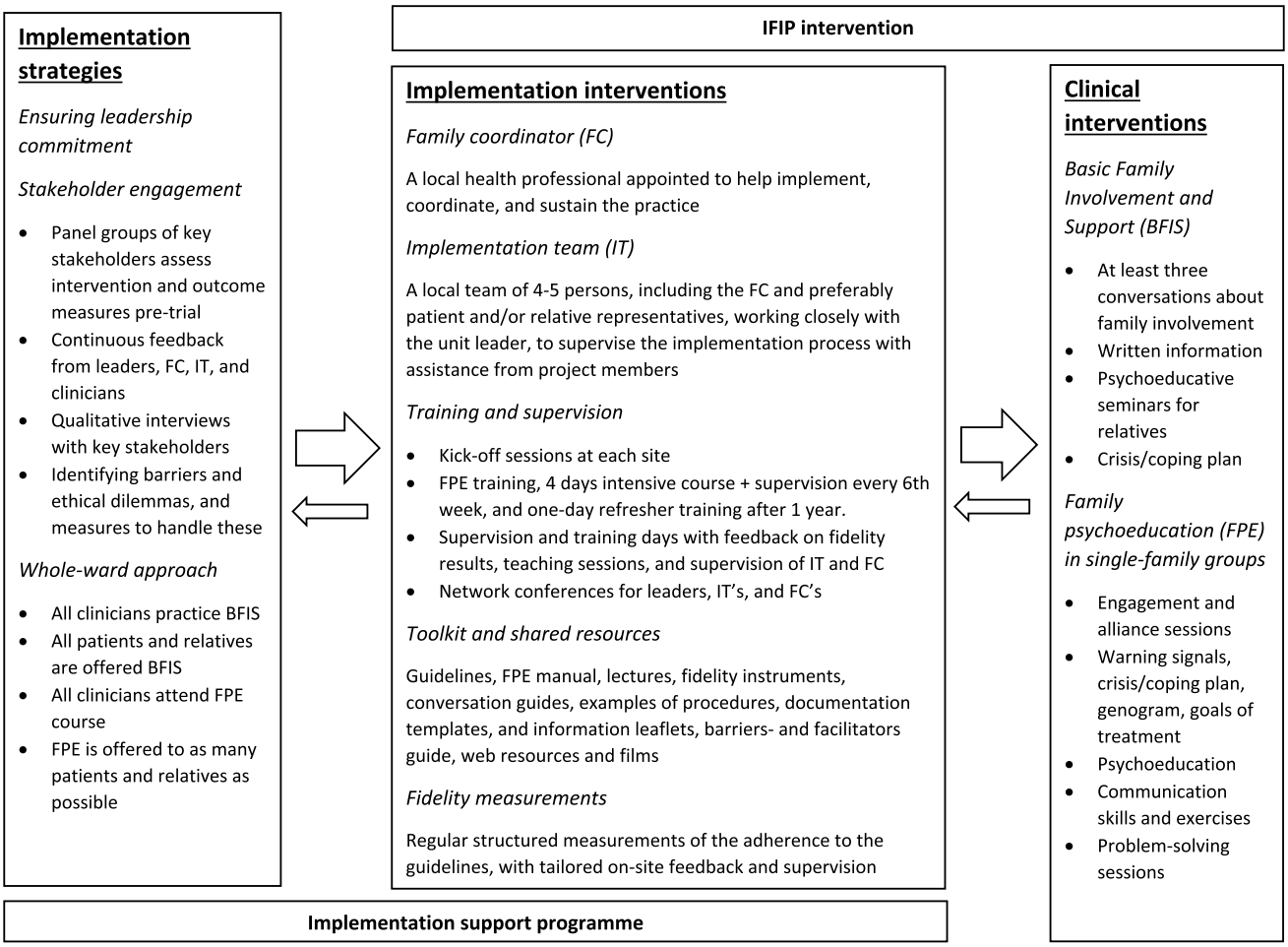

Fig. 2 The IFIP intervention and Implementation support programme (ISP)

Randomisation

Figure 1 illustrates the flow of clusters through recruitment, allocation, and analysis. The project group generated a sequence by ranking the clusters according to their number of patients with psychotic disorders. The clusters were then stratified into three even-numbered blocks, and within each block, they were randomised to the experimental or control arm with an allocation ratio of 1:1. An independent and blinded statistician performed the allocation by drawing 14 numbers with the Microsoft Excel RAND function.

Intervention

The project group developed the IFIP intervention to operationalise the national guidelines. An elaborate description of the intervention and its development can be found in the study protocol (Hestmark et al., 2020). A qualitative exploration of the implementation process, in terms of barriers and facilitators, has also been published (Hansson et al., 2022).

Figure 2 displays the implementation strategies, implementation interventions, and clinical interventions of the IFIP trial, and how these were connected through continuous feedback loops. It also illustrates how 'The IFIP intervention' refers to both the implementation- and clinical interventions of the trial, whereas 'The implementation support programme' (ISP) refers to all the strategies and activities intended to support the implementation of the clinical interventions. The experimental clusters received the ISP for 18 months, whereas the control clusters did not receive such support during this period.

The ISP was based on the seminal work of the National Evidence-Based Practices (NEBP) project (Bond et al., 2009a; McHugo et al., 2007), and on a recent Norwegian RCT (Ruud et al., 2021). We adopted elements such as the constitution of a local implementation team, regular fidelity measurements with tailored feedback and on-site supervision, kick-off sessions, training and supervision

in FPE, a toolkit, a local programme coordinator (family coordinator), interviews with leaders and practitioners, mapping of barriers and facilitators, and a particular emphasis on leadership commitment. Each clinical site had a regular contact person from the research team, developing a continuous working relationship with the local leader(s), implementation team, and family coordinator. The researchers who measured fidelity also conducted the supervision of the local implementation teams, using the recent fidelity results to identify areas for improvement and make detailed 6-month plans for implementation activities, as part of on-site 'Training and supervision days'. The latter also included plenary sessions with all the clinicians at the unit, with feedback on fidelity results, presentation and discussion of goals set by the implementation team, training in how to handle the duty of confidentiality during family involvement, and presentations of relevant tools. Training and supervision in FPE was provided by The Early Intervention in Psychosis Advisory Unit for South East Norway. The role of the family coordinator was comprehensive and intended as a permanent part of the organisation to promote sustainability of the new practice.

In addition, the IFIP trial employed several distinct implementation strategies: Stakeholder engagement inspired by a responsive evaluation approach (Abma, 2006), a whole-ward approach (Sævareid et al., 2019), and the combination of FPE and Basic Family Involvement and Support (BFIS) (Hestmark et al., 2020, 2021). Throughout the trial, we interviewed key stakeholders and received feedback from the participating units, as part of a responsive process evaluation, to adjust the implementation strategy and effort. This interactive approach was further employed to investigate key barriers and ethical dilemmas, and to identify possible solutions and facilitators for implementation (Hansson et al., 2022).

The whole-ward approach was intended to alter the culture and clinical modus operandi of entire health care units (Sævareid et al., 2019). Since awareness, attitudes, and clinical skills varied considerably when it came to family involvement, we recommended that all clinicians should receive FPE training to gain a shared understanding and appreciation of its benefits (Mottaghipour et al., 2006). A second feature of this approach was the recommendation that all clinical personnel should acquire BFIS skills, and provide such services to all patients with psychotic disorders and their relatives. The diffusion of awareness, competence, and skills was also intended as a sustainability measure, to render the new practice less vulnerable to staff turnover. By promoting BFIS, we sought to increase the frequency of contact between relatives and health personnel, potentially leading to increased levels of FPE as well.

There were no specific qualifications required for being appointed as a family coordinator or implementation team member, or for delivering BFIS and FPE, other than the training and supervision offered as part of the trial.

Instruments

We employed three fidelity scales to assess the adherence to the national guidelines. The scales consist of 12–14 items rated from 1 to 5, where 1 equals no implementation and 5 equals full implementation.

To measure basic family involvement and support (BFIS), the project group developed a new 14-item fidelity scale with two subscales. One subscale (BFIS-S) examines structure, content, and implementation, while the other (BFIS-P) measures 'penetration rate'. The latter term means the percentage of eligible patients and/or relatives that receive a particular intervention. A description of the development process, content, and psychometric properties of the BFIS scale has been published (Hestmark et al., 2021). Due to limited time for piloting, some items were removed or changed after the baseline data were collected, resulting in minor adjustments of the baseline scores.

The 14-item family psychoeducation fidelity assessment (FPE) scale rates the practice and content of FPE, whereas the 12-item general organizational index (GOI) scale measures the individualisation, quality improvement, program philosophy, and penetration rate of FPE. Previous studies report acceptable psychometric properties for both scales (Bond et al., 2009b; Heiervang et al., 2020; Joa et al., 2020; Kealey et al., 2015). An average score of 4 or above on either scale denotes adequate implementation, while scores below 4 indicate moderate to low implementation. Sites that did not offer FPE were scored 1 on all items on both scales. Item 7: 'prodromal signs' in the FPE scale was omitted, since the participating sites rarely treated patients with prodromal or ultra-high risk states.

Data Collection

The timeline in Supplementary file 2 shows the intervals between fidelity measurements in the experimental arm. The official start of the implementation period was 6 months after the baseline fidelity measurements, with the first follow-up measurements 6 months later and then every 6th month throughout the trial. Fidelity assessments in the control arm were only performed at baseline and 24 months. When measuring fidelity at baseline and 12 months, the assessors visited the clinical sites. However, because of the coronavirus pandemic, we had to employ a digital video conference platform for some of the measurements at 18 months, and all of the measurements at 24 months.

At each site, two researchers measured fidelity by conducting structured interviews with leaders, clinicians, and resource persons, and by examining written material

such as procedures and information leaflets. They performed 2–5 separate interviews of 1–1.5 h length. Usually the head of department was interviewed individually, whereas those in other participant categories were interviewed in groups of 2–6 persons. Verbal informed consent was obtained from all participants prior to the interviews. The two fidelity assessors first scored all items independently and then resolved any discrepancies to reach a consensus score for each item. Where clusters consisted of subunits with differing clinical approaches and patient populations, their average scores were recorded. The two experimental sites that were merged to a single cluster were scored separately throughout the trial, and their average scores were calculated at each time point as the cluster scores. We solely assessed the sites' practice towards patients with psychotic disorders and their relatives. At each time point, we also recorded the percentage of patients with psychotic disorders that had received or were receiving FPE, based on administrative data. When calculating these percentages, the denominator only included patients currently receiving treatment at the clinical unit.

The assessors, and the pairing of them, varied across both sites and time points. None of the five researchers who assessed fidelity throughout the trial were employees of the clinical sites in the study. At each time point, the fidelity assessors prepared a detailed report for the respective site to complement the scores. Scores and reports were made available to the sites in the experimental arm, but not to the sites in the control arm, to reduce the influence of fidelity assessments on their practice during the implementation period. Due to obvious changes in the practice and organisation of experimental sites, and the fact that researchers provided implementation support, it was impossible to blind the assessments.

Data Analyses

To assess interrater reliability (IRR), we calculated the intra-class correlation coefficient (ICC) for each scale's total mean fidelity, using a one-way random effects analysis of variance model for agreement between two assessors.

In accordance with the premises of the sample size calculation, difference between experimental and control arms in change on the FPE scale (primary outcome) from baseline to 24 months, was assessed by an Independent samples t-test. The results were presented as mean difference with corresponding 95% confidence interval (CI), p-value and effect size (Cohen's d) with 95% CI.

Differences between the experimental and control arms in change on the FPE scale, the GOI scale, the BFIS scale, and its subscales BFIS-S and BFIS-P were assessed by linear mixed models (LMMs) with random intercepts for clusters. Random effects for Health trust were also considered, but skipped, as the model fit was not improved according to Bayes Information Criterion. To account for potentially non-linear trend through four time points in the experimental arm and model linear trend in the control arm with measurements at two time points only, we estimated the following model with respect to fixed effects:

$$y = \beta_0 + \beta_1^* \text{Group} + \beta_2^* t_{12}^* \text{Group} + \beta_3^* t_{18}^* \text{Group} + \beta_2^* t_{24} + \beta_5^* t_{24}^* \text{Group},$$

where t_{12}, t_{18} and t_{24} are dummies for time, Group is dummy for group (0 for control and 1 for experimental group), and t_{12}*Group, t_{18}*Group and t_{24}*Group are interactions between time dummies and group dummy. Differences in change in the percentage of patients receiving FPE were analysed with a tobit regression model for longitudinal data with the same fixed and random effects as above. A priori planned adjustment for the stratification variable was explored.

Post hoc analyses, not planned a priori, were performed to assess within-group changes as well as between-group differences and between-group differences in changes. The results were presented as observed means and standard deviations (SDs) and mean changes and differences with corresponding 95% CIs and p-values as well as effect sizes (Cohen's d) with 95% CIs estimated from LMM or tobit model. The results with p-values below 0.05 were considered statistically significant. No adjustment for multiple testing was performed, as the post hoc analyses were of exploratory nature. Standard residual diagnostic was performed. Data analyses were performed using IBM SPSS statistics version 28 and STATA version 17.

Results

Concerning IRR, we calculated an ICC of 0.99 for mean total fidelity of the BFIS scale, based on all 46 fidelity measurements. With regard to the FPE scale, we estimated an ICC of 0.99 for mean total fidelity, and the ICC of the GOI scale was 0.99. When calculating ICC for the GOI and FPE scales, we only included the 34 fidelity measurements where the unit in question offered FPE.

Mean difference between the study arms in change on the FPE scale from baseline to 24 months was 2.69 with 95% CI (0.67; 4.71), $p = 0.013$, and effect size 1.55 (0.32; 2.75).

The results of the linear mixed models and the tobit regression model are reported in Table 1. It shows that the increase in fidelity scores on all scales and BFIS subscales from baseline to 24 months was significantly larger for experimental clusters than control clusters with p-values < 0.001. The difference in change in the percentage of patients receiving FPE was also significant with $p = 0.01$.

Table 1 Results of linear mixed models and tobit regression model for difference in change between the experimental and control arm

	BFIS mean[b]		BFIS-S mean[b]		BFIS-P mean[b]		GOI mean[b]		FPE scale mean[b]		FPE % mean[c]	
	RC (SE)	p-value	RC (SE)	p-value	RC (SE)	p-value	RC (SE)	p-value	RC (SE)	p-value	RC (SE)	p-value
Intercept	2.25 (0.16)	< 0.001	1.66 (0.16)	< 0.001	2.59 (0.17)	< 0.001	1.77 (0.21)	< 0.001	2.87 (0.47)	< 0.001	1.19 (3.88)	0.760
Group[a]	0.22 (0.22)	0.320	0.09 (0.23)	0.705	2.29 (0.25)	0.232	0.04 (0.30)	0.889	−0.14 (0.67)	0.837	2.92 (5.41)	0.589
T12 x Group	1.01 (0.14)	**< 0.001**	1.71 (0.14)	**< 0.001**	0.61 (0.16)	**< 0.001**	2.12 (0.24)	**< 0.001**	1.18 (0.51)	**0.020**	10.61 (2.67)	**< 0.001**
T18 x Group	1.30 (0.14)	**< 0.001**	1.93 (0.14)	**< 0.001**	0.95 (0.16)	**< 0.001**	2.22 (0.24)	**< 0.001**	1.71 (0.51)	**0.001**	10.03 (2.67)	**< 0.001**
T24	0.11 (0.14)	0.407	−0.03 (0.14)	0.836	0.19 (0.16)	0.245	−0.37 (0.24)	0.125	−0.94 (0.51)	0.062	−1.27 (2.83)	0.653
T24 x Group	1.41 (0.19)	**< 0.001**	2.29 (0.19)	**< 0.001**	0.93 (0.23)	**< 0.001**	2.56 (0.34)	**< 0.001**	2.69 (0.72)	**< 0.001**	10.00 (3.88)	**0.010**

Statistically significant *p*-values are given in bold

[a]Control arm—reference

[b]Linear mixed model

[c]Tobit regression model for longitudinal outcome

Adjustment for the stratification variable did not affect the results (Supplementary file 3).

The descriptive statistics reported in Table 2 show that the mean scores among experimental clusters at 24 months were ≥ 4.00 on all scales, whereas the corresponding mean scores in the control arm were < 3.00. Estimated mean fidelity scores at each time point, with 95% CIs, are depicted for both arms in Fig. 3.

Table 3 displays the post hoc analyses of mean fidelity changes within arms and the mean differences in change between arms for each time interval. The changes in fidelity between baseline and 24 months in the control arm were not significant on any scale. In the experimental arm, the changes between baseline and 12, 18, and 24 months were significant on all scales and subscales. The differences in fidelity changes between experimental and control arms between baseline and 24 months were all significant, and the corresponding effect sizes were substantial.

At baseline, 4 of 7 clusters in both arms offered FPE. However, at 24 months, all of the clusters in the experimental arm offered FPE, while only 2 clusters in the control arm did so. Table 2 displays how the mean percentage of patients with psychotic disorders, previously or currently receiving FPE, approximately doubled from 6.76 to 12.84% in the experimental arm, whereas it fell from 4.09 to 2.99% in the control arm. Post hoc analyses showed that the changes between baseline and 12, 18, and 24 months in the experimental arm were all significant, and the difference in change between arms from baseline to 24 months was also significant with p = 0.01.

Discussion

The results show that the ISP had a significant and substantial effect on the adherence to the national guidelines in participating clusters, compared to manual/guideline only. At 24 months, the mean scores on all fidelity scales were four or higher in the experimental arm, suggesting adequate to excellent levels of implementation.

Structural elements of the BFIS scale such as implementation team, family coordinator, and procedures for family involvement were implemented during the first 6 months of the implementation period in the experimental arm, as demonstrated by the sharp rise in BFIS-S scores. By comparison, the BFIS-P scores increased progressively throughout the trial, probably reflecting that time is required for organisational and procedural changes to reach patients and relatives (Bond et al., 2009a, b; McHugo et al., 2007).

At 24 months, all experimental sites offered FPE with adequate fidelity (≥ 4) and a mean score of 4.48. The progressive nature of the FPE model probably explains

Table 2 Descriptive statistics for outcome variables and results of post hoc analysis from linear mixed models and tobit regression model for between-arm differences

Time point	Experimental arm Mean (SD)[1]	Control arm Mean (SD)[1]	Experimental vs. control arm Mean difference (95% CI)[2]
BFIS mean			
0	2.47 (0.63)	2.25 (0.16)	0.22 (−0.21; 0.65)
12	3.48 (0.56)		
18	3.78 (0.51)		
24	4.00 (0.37)	2.37 (0.41)	1.63 (1.20; 2.06)
BFIS-S mean			
0	1.74 (0.60)	1.66 (0.19)	0.09 (−0.36; 0.53)
12	3.46 (0.59)		
18	3.67 (0.54)		
24	4.00 (0.37)	1.63 (0.47)	2.37 (1.93; 2.82)
BFIS-P mean			
0	2.88 (0.70)	2.59 (0.24)	0.29 (−0.19; 0.77)
12	3.49 (0.61)		
18	3.84 (0.55)		
24	4.00 (0.43)	2.78 (0.41)	1.22 (0.74; 1.80)
GOI mean			
0	1.82 (0.91)	1.77 (0.76)	0.04 (−0.54; 0.62)
12	3.94 (0.27)		
18	4.04 (0.23)		
24	4.01 (0.22)	1.40 (0.69)	2.60 (2.02; 3.19)
FPE scale mean			
0	2.73 (1.77)	2.87 (1.76)	−0.14 (−1.44; 1.17)
12	3.91 (1.21)		
18	4.44 (0.21)		
24	4.48 (0.22)	1.92 (1.58)	2.55 (1.25; 3.86)
FPE % mean			
0	6.76 (6.88)	4.09 (4.62)	2.92 (−7.68; 13.52)
12	14.71 (14.10)		
18	14.14 (9.43)		
24	12.84 (11.92)	2.99 (4.62)	12.93 (2.52; 23.34)

[1]Observed mean and standard deviation (SD)

[2]Mean difference and 95% confidence interval (CI) estimated from linear mixed model or tobit regression for longitudinal data (for FPE % mean)

the gradual increase in scores in the experimental arm. The success rate is good compared to previous studies, which report mean scores of 3.30–4.00 and 39–50% of sites reaching adequate fidelity after 18–24 months of implementation support (Bond et al., 2009a, b; Kealey et al., 2015; Ruud et al., 2021). However, these studies experienced high rates of discontinuation or unsuccessful implementation. Similarly to previous studies (Kealey et al., 2015; McHugo et al., 2007), the major increase in FPE fidelity happened in the first 12 months of the implementation period.

The GOI scale was used to investigate critical implementation factors beyond fidelity (Heiervang et al., 2020). A mean score across sites of 4.01, with 71% of sites reaching an adequate mean score (≥ 4) at 24 months constitute excellent results, compared to previous studies who report mean scores of 2.99–4.10 and 18–50% of sites reaching adequate levels after 12–24 months of implementation support for Illness Management and Recovery (Egeland et al., 2017; Heiervang et al., 2020; Salyers et al., 2009).

The substantial improvements in FPE fidelity and GOI scores in the experimental arm were not accompanied by large increases in the penetration rate of FPE. This might be related to capacity issues, the relatively short observation time, and the coronavirus pandemic (see below). By not including discharged patients who had received FPE, the numbers may also systematically

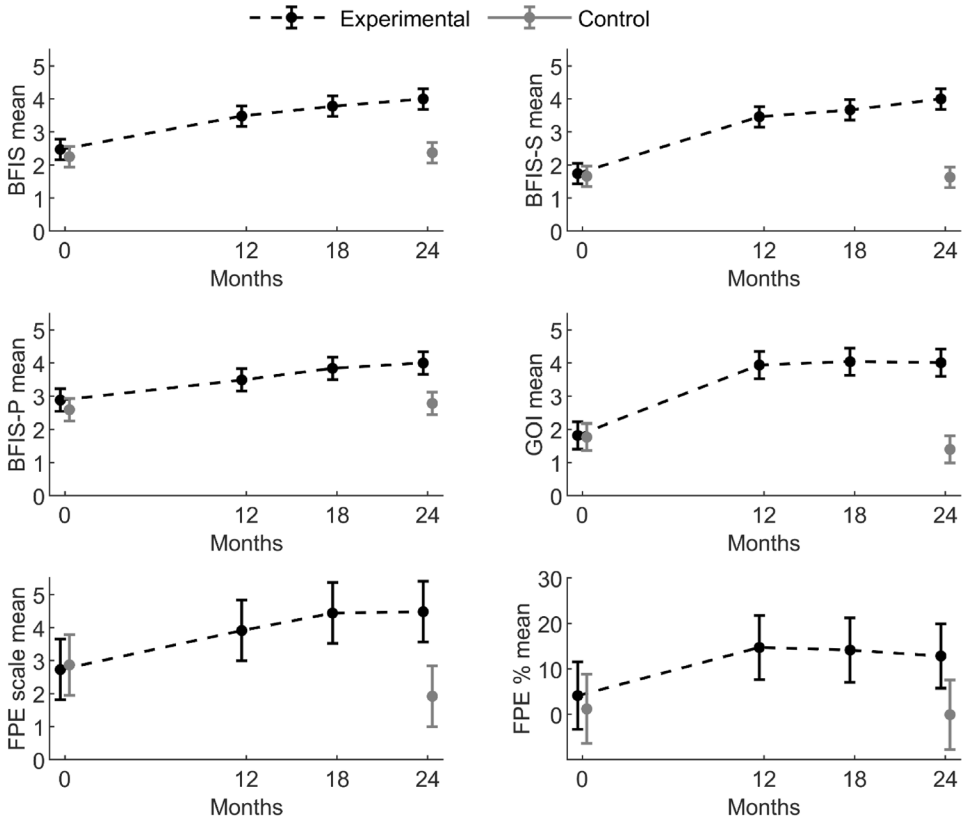

Fig. 3 Mean fidelity scores with 95% CIs in experimental and control clusters from baseline to 24 months. Results of linear mixed models and tobit regression model

underestimate the effort of the clinical sites. In contrast, the mean score on the BFIS-P subscale indicates that the penetration rate of basic family involvement practices rose to 60–80% across items in the experimental arm at 24 months. BFIS practices are less time-consuming than FPE and were usually implemented as standardised procedures towards all patients at the clinical sites, which may explain some of the difference in penetration rate. When calculating the penetration rates, we assumed that all patients with psychotic disorders were eligible for BFIS and FPE, which probably is an overestimation, particularly with regard to FPE (Haahr et al., 2021).

Similar to the implementation model of the NEBP project (Bond et al., 2009a, b), a central strategy was to use the fidelity scores actively to guide the implementation process in experimental sites, where the fidelity assessors supervised the local leader(s), implementation team, and family coordinator. Qualitative data indicate that this external support was a critical facilitator for implementation (Hansson et al., 2022).

The IFIP implementation strategy also differed from those of previous multi-centre fidelity-based studies on the implementation of FPE (Kealey et al., 2015; McHugo et al., 2007; Ruud et al., 2021). Implementing BFIS alongside FPE may have reinforced the adoption of both by the clinical sites. Introducing routines for early and systematic contact with relatives of all patients with psychotic disorders, by all clinicians, may have lowered the threshold for initiating advanced levels of family involvement, such as FPE (Hansson et al., 2022; Mottaghipour & Bickerton, 2005). By only targeting patients with psychotic disorders, and implementing single-family psychoeducation groups rather than multi-family groups or both, the project aimed to simplify the implementation- and recruitment processes for the sites.

The first coronavirus pandemic lockdown in Norway began approximately 2 months before the fidelity measurements at 18 months. The consequent lack of newly started FPE groups in the last 7–8 months of the implementation period contributed to the dip in FPE penetration rate seen at 18 and 24 months. Fidelity scores did not appear to be similarly affected, but it is difficult to ascertain whether the results could have been different. The lack of data points at 12 and 18 months in the control arm makes it harder to assess the influence of such external factors, but it is likely that the respective arms were affected to the same degree.

Strengths and Limitations

As a pragmatic cluster randomised trial in a real-world setting, with clinical sites covering 25% of the Norwegian

Table 3 Mean changes and between-group differences in changes with 95% CIs. Results of post hoc analysis from linear mixed models and tobit regression model

Interval	Experimental arm		Control arm		Experimental vs. control arm		
	Mean change (95% CI)	p-value	Mean change (95% CI)	p-value	Mean change (95% CI)	p-value	Cohen's d (95% CI)
BFIS mean							
0–12	1.01 (0.74; 1.28)	< 0.001	0.11 (− 0.16; 0.38)	0.407	1.41 (1.03; 1.79)	< 0.001	3.41 (1.69; 5.13)
0–18	1.30 (1.03; 1.57)	< 0.001					
0–24	1.52 (1.25; 1.79)	< 0.001					
12–18	0.29 (0.02; 0.56)	0.033					
12–24	0.52 (0.25; 0.79)	< 0.001					
18–24	0.22 (− 0.05; 0.49)	0.106					
BFIS-S mean							
0–12	1.71 (1.44; 1.98)	< 0.001	− 0.03 (− 0.30; 0.24)	0.836	2.29 (1.90; 2.67)	< 0.001	5.40 (3.00; 7.80)
0–18	1.93 (1.66; 2.20)	< 0.001					
0–24	2.26 (1.99; 2.53)	< 0.001					
12–18	0.21 (− 0.06; 0.48)	0.120					
12–24	0.54 (0.27; 0.81)	< 0.001					
18–24	0.33 (0.06; 0.60)	0.017					
BFIS-P mean							
0–12	0.61 (0.29; 0.93)	< 0.001	0.19 (− 0.13; 0.51)	0.245	0.93 (0.48; 1.38)	< 0.001	2.03 (0.70; 3.35)
0–18	0.95 (0.63; 1.27)	< 0.001					
0–24	1.12 (0.80; 1.44)	< 0.001					
12–18	0.34 (0.02; 0.66)	0.036					
12–24	0.51 (0.19; 0.83)	0.002					
18–24	0.17 (− 0.15; 0.49)	0.310					
GOI mean							
0–12	2.12 (1.65; 2.60)	< 0.001	− 0.37 (− 0.84; 0.10)	0.125	2.56 (1.89; 3.23)	< 0.001	4.60 (2.49; 6.72)
0–18	2.22 (1.75; 2.69)	< 0.001					
0–24	2.19 (1.72; 2.66)	< 0.001					
12–18	0.10 (− 0.38; 0.57)	0.687					
12–24	0.07 (− 0.41; 0.54)	0.781					
18–24	− 0.03 (− 0.50; 0.44)	0.901					
FPE scale mean							
0–12	1.18 (0.19; 2.17)	0.020	− 0.94 (− 1.94; 0.05)	0.062	2.69 (1.29; 4.09)	< 0.001	2.16 (0.80; 3.52)
0–18	1.71 (0.72; 2.70)	0.001					
0–24	1.75 (0.76; 2.74)	0.001					
12–18	0.53 (− 0.46; 1.52)	0.293					
12–24	0.57 (− 0.42; 1.56)	0.260					
18–24	0.04 (− 0.95; 1.03)	0.939					
FPE % mean							
0–12	10.6 (5.4; 15.8)	< 0.001	− 1.3 (− 6.8; 4.3)	0.653	10.0 (2.4; 17.6)	0.010	1.00 (− 0.12; 2.12)
0–18	10.0 (4.8; 15.3)	< 0.001					
0–24	8.7 (3.5; 14.0)	0.001					
12–18	− 0.6 (− 5.3; 4.1)	0.812					
12–24	− 1.9 (− 6.6; 2.8)	0.436					
18–24	− 1.3 (− 6.0; 3.4)	0.588					

population, the findings may be considered robust and relevant to similar implementation efforts in the health services. To our knowledge, the IFIP trial is the first large-scale effort to implement basic family involvement practices in CMHCs, and the BFIS scale is the first instrument to assess such practices systematically.

In terms of external validity, our results describe practices towards a specific patient group and their relatives, in a particular clinical, geographical, and cultural context. Still, the generic character of many of the interventions and implementation strategies used suggests that these may be suitable in other clinical settings as well. By providing continuous feedback on the results (formative assessment), the external validity of the findings is limited to interventions that employ a similar implementation strategy (Lilford et al., 2009).

The study design could have been more suitable to evaluate the implementation strategy, if there was a 'placebo' implementation strategy in the control arm. However, this would have resulted in contamination of

the sub study on patients' and relatives' outcomes. Since participants and researchers could not be blinded, there is a possibility that the sites' allocation status influenced both the performance and evaluation of the respective arms. It was a deliberate and pragmatic decision to have the fidelity reviewers provide implementation support and supervision, because the insights gained through fidelity measurements enabled them to tailor the supervision to the respective unit's needs. However, one could argue that they consequently assessed some of the results of their own effort, which introduced a risk of experimenter bias. This is most relevant when considering the results measured with the GOI scale and the BFIS subscale that examined structure, content, and implementation (BFIS-S). Both scales contain structural, procedural, and organisational elements, which level of implementation was influenced by the fidelity assessors through their supervision of the implementation teams. Yet, many of these elements are less susceptible to experimenter bias, because they are less open to interpretation. Examples include whether or not units had written information, procedures on family involvement, appointed a family coordinator, constituted an implementation team, or the percentage of clinical staff with FPE training. Since training and supervision in FPE was provided by an independent organisation, which had nothing to do with fidelity assessments, the results measured with the FPE scale (primary outcome) were not subject to a similar risk of experimenter bias.

By removing or altering a few elements of the BFIS scale after the baseline measurements, we potentially risked introducing bias and overestimating the intervention effect, if elements were removed that appeared hard to implement. However, the elements removed were covered by the other scales and the elements altered were generally made stricter and more specific. Fidelity raters did not observe FPE sessions, interview service users, or assess randomly selected patient records, all of which could have increased the validity of our findings. Concerning predictive validity, the present paper does not report on patients' and relatives' outcomes, but such data will be analysed and reported on later as part of the trial.

Implications

The findings of the IFIP trial can and should be employed to scale up family involvement practices for persons with psychotic disorders in CMHCs. Research is needed on the sustainability of family involvement practices, on methods to scale up efficiently, on implementation for other patient groups with severe mental illness, and on implementation in other health- and care contexts, such as inpatient facilities and municipal health services.

Conclusion

This study demonstrates that large-scale implementation of guidelines on family involvement for persons with psychotic disorders in CMHCs may be accomplished, with substantial implementation support combining general and specific implementation strategies.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10488-023-01255-0.

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Author Contributions All authors, with the exception of JSB, made significant contributions to the conception and design of the study, with particularly substantial contributions from KSH, TR, and RP. LH and KSH developed the BFIS fidelity scale with input from the other authors. MR did a preliminary mapping of the participating units' structure, organisation and practice, and made substantial efforts to recruit clinical units with aid from the other authors. KSH provided training in fidelity measurement to the fidelity assessors. MR, LH and KMH did most of the data collection, with assistance from RP and KSH. Statistical analyses were mainly carried out by JSB, with assistance from LH. LH wrote the first draft of this article. All the authors critically revised the article, gave their final approval before submission, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Data Availability The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest The authors have no competing interests to declare that are relevant to the content of this article.

Consent to Publish Not applicable.

Ethical Approval The study has been approved by the Norwegian regional committee for medical and health research ethics (REC) South East with Registration Number 2018/128. REC provides a general ethical approval to conduct the study as described in recruited clinical units. On the advice of local data protection officers at the trial sites, the PI on behalf of the University of Oslo has signed contracts on shared responsibility for data processing with each participating health care trust, allowing us to carry out the study at each trial site in accordance with the General Data Protection Regulation. In the study reported here, informed consent was obtained verbally from all the

interview participants. No personal data or information was collected from the participants and no transcripts or recordings were made of the interviews. Fidelity scores and reports were the only data produced. All the methods reported here were performed in accordance with the ethics committee approval, national legal regulations and guidelines for research ethics, and the WMA declaration of Helsinki.

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Additional file 2 (Article 3)

Supplementary file 2. Timeline for the experimental clusters (n =7) of the IFIP trial.

Activity | Month	0[1]	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Fidelity measurements	X	X											X	X					X	X					X	X
Randomisation			X																							
Kick-off sessions					X	X																				
Supervision and training days							X	X							X	X							X	X		
FPE training					X	X	X	X																		
FPE supervision every 6th week									X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Network conferences											X						X					X				
FPE refresher training																X	X	X								
External factors																										
Sars-COV-2 Pandemic																	X	X	X	X	X	X	X	X	X	X

[1] November 2018.

Additional file 3 (Article 3)

Supplementary file 3. Results of linear mixed models and tobit regression model for difference in change between the experimental and control arm, adjusted for stratification variable.

	BFIS mean[b]		**BFIS-S mean**[b]		**BFIS-P mean**[b]		**GOI mean**[b]		**FPE scale mean**[b]		**FPE % mean**[c]	
	RC (SE)	p-value	RC (SE)	p-value	RC (SE)	p-value	RC (SE)	p-value	RC (SE)	p-value	RC (SE)	p-value
Intercept	2.39 (0.18)	<0.001	1.79 (0.19)	<0.001	2.72 (0.20)	<0.001	1.90 (0.21)	<0.001	3.29 (0.45)	<0.001	3.20 (3.74)	0.393
Group[a]	0.22 (0.21)	0.300	0.09 (0.22)	0.694	2.29 (0.24)	0.217	0.04 (0.27)	0.876	-0.14 (0.55)	0.805	3.06 (3.84)	0.424
T12 x Group	1.01 (0.14)	**<0.001**	1.71 (0.14)	**<0.001**	0.61 (0.16)	**<0.001**	2.12 (0.24)	**<0.001**	1.18 (0.52)	**0.022**	10.62 (3.29)	**0.001**
T18 x Group	1.30 (0.14)	**<0.001**	1.93 (0.14)	**<0.001**	0.95 (0.16)	**<0.001**	2.22 (0.24)	**<0.001**	1.71 (0.52)	**0.001**	10.05 (2.43)	**<0.001**
T24	0.11 (0.14)	0.406	-0.03 (0.15)	0.835	0.19 (0.16)	0.244	-0.37 (0.24)	0.128	-0.94 (0.52)	0.067	-1.06 (2.86)	0.711
T24 x Group	1.41 (0.19)	**<0.001**	2.29 (0.19)	**<0.001**	0.93 (0.23)	**<0.001**	2.56 (0.34)	**<0.001**	2.69 (0.73)	**<0.001**	9.81 (4.36)	**0.024**
Stratum												
1	-0.19 (0.22)	0.384	-0.20 (0.23)	0.369	-0.18 (0.24)	0.450	0.06 (0.22)	0.780	-0.01 (0.44)	0.978	2.61 (6.16)	0.672
2 – ref.	0		0		0		0		0		0	
3	-0.27 (0.222)	0.215	-0.27 (0.23)	0.240	-0.28 (0.24)	0.247	-0.50 (0.22)	0.019	-1.45 (0.44)	0.001	-10.20 (3.29)	0.002

[a] Control group – reference; [b] Linear mixed model; [c] Tobit regression model for longitudinal outcome

Correction (Article 3)

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CORRECTION

Correction to: Implementation of Guidelines on Family Involvement for Persons with Psychotic Disorders (IFIP): A Cluster Randomised Controlled Trial

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Correction to: Administration and Policy in Mental Health and Mental Health Services Research (2023) 50:520–533
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The original version of the article unfortunately contained a mistake in Table 3, which was introduced during formatting. The correct version of Table 3 is given below.

The online version of the original article can be found at https://doi.org/10.1007/s10488-023-01255-0.

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Table 3 Mean changes and between-group differences in changes with 95% CIs. Results of post hoc analysis from linear mixed models and tobit regression model

Interval	Experimental arm		Control arm		Experimental vs. Control arm		
	Mean change (95% CI)	p-value	Mean change (95% CI)	p-value	Mean change (95% CI)	p-value	Cohen's d (95% CI)
BFIS mean							
0–12	1.01 (0.74; 1.28)	< 0.001					
0–18	1.30 (1.03; 1.57)	< 0.001					
0–24	1.52 (1.25; 1.79)	< 0.001	0.11 (-0.16; 0.38)	0.407	1.41 (1.03; 1.79)	< 0.001	3.41 (1.69; 5.13)
12–18	0.29 (0.02; 0.56)	0.033					
12–24	0.52 (0.25; 0.79)	< 0.001					
18–24	0.22 (-0.05; 0.49)	0.106					
BFIS-S mean							
0–12	1.71 (1.44; 1.98)	< 0.001					
0–18	1.93 (1.66; 2.20)	< 0.001					
0–24	2.26 (1.99; 2.53)	< 0.001	-0.03 (-0.30; 0.24)	0.836	2.29 (1.90; 2.67)	< 0.001	5.40 (3.00; 7.80)
12–18	0.21 (-0.06; 0.48)	0.120					
12–24	0.54 (0.27; 0.81)	< 0.001					
18–24	0.33 (0.06; 0.60)	0.017					
BFIS-P mean							
0–12	0.61 (0.29; 0.93)	< 0.001					
0–18	0.95 (0.63; 1.27)	< 0.001					
0–24	1.12 (0.80; 1.44)	< 0.001	0.19 (-0.13; 0.51)	0.245	0.93 (0.48; 1.38)	< 0.001	2.03 (0.70; 3.35)
12–18	0.34 (0.02; 0.66)	0.036					
12–24	0.51 (0.19; 0.83)	0.002					
18–24	0.17 (-0.15; 0.49)	0.310					
GOI mean							
0–12	2.12 (1.65; 2.60)	< 0.001					
0–18	2.22 (1.75; 2.69)	< 0.001					
0–24	2.19 (1.72; 2.66)	< 0.001	-0.37 (-0.84; 0.10)	0.125	2.56 (1.89; 3.23)	< 0.001	4.60 (2.49; 6.72)
12–18	0.10 (-0.38; 0.57)	0.687					
12–24	0.07 (-0.41; 0.54)	0.781					
18–24	-0.03 (-0.50; 0.44)	0.901					
FPE scale mean							
0–12	1.18 (0.19; 2.17)	0.020					
0–18	1.71 (0.72; 2.70)	0.001					
0–24	1.75 (0.76; 2.74)	0.001	-0.94 (-1.94; 0.05)	0.062	2.69 (1.29; 4.09)	< 0.001	2.16 (0.80; 3.52)
12–18	0.53 (-0.46; 1.52)	0.293					
12–24	0.57 (-0.42; 1.56)	0.260					
18–24	0.04 (-0.95; 1.03)	0.939					
FPE % mean							
0–12	10.6 (5.4; 15.8)	< 0.001					
0–18	10.0 (4.8; 15.3)	< 0.001					
0–24	8.7 (3.5; 14.0)	0.001	-1.3 (-6.8; 4.3)	0.653	10.0 (2.4; 17.6)	0.010	1.00 (-0.12; 2.12)
12–18	-0.6 (-5.3; 4.1)	0.812					
12–24	-1.9 (-6.6; 2.8)	0.436					
18–24	-1.3 (-6.0; 3.4)	0.588					

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Clinicians' perceptions of family involvement in the treatment of persons with psychotic disorders: a nested qualitative study

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Background: Family involvement in mental health care ranges from basic practices to complex interventions such as Family psychoeducation, the latter being a well-documented treatment for psychotic disorders. The aim of this study was to explore clinicians' perceptions of the benefits and disadvantages of family involvement, including possible mediating factors and processes.

Methods: Nested in a randomised trial, which purpose was to implement Basic family involvement and support and Family psychoeducation in Norwegian community mental health centres during 2019–2020, this qualitative study is based on eight focus groups with implementation teams and five focus groups with ordinary clinicians. Using a purposive sampling strategy and semi-structured interview guides, focus groups were audio-recorded, transcribed verbatim, and analysed with reflexive thematic analysis.

Results: Four main themes were identified as perceived benefits: (1) Family psychoeducation—a concrete framework, (2) Reducing conflict and stress, (3) A triadic understanding, and (4) Being on the same team. Themes 2–4 formed an interconnected triad of mutually reinforcing elements and were further linked to three important clinician-facilitated sub-themes: a space for relatives' experiences, emotions and needs; a space for patients and relatives to discuss sensitive topics and an open line of communication between clinician and relative. Although far less frequent, three main themes were identified as perceived disadvantages or challenges: (1) Family psychoeducation—occasional poor model fit or difficulties following the framework, (2) Getting more involved than usual, and (3) Relatives as a potentially negative influence—important nonetheless

Conclusions: The findings contribute to the understanding of the beneficial processes and outcomes of family involvement, as well as the critical role of the clinician in achieving these and possible challenges. They could also be used to inform future quantitative research on mediating factors and implementation efforts.

KEYWORDS

family involvement, psychotic disorders, family psychoeducation, qualitative methods, mental health services research

1. Introduction

Persons with psychotic disorders may experience positive symptoms, such as hallucinations and delusions, and negative symptoms, such as social withdrawal, emotional apathy, and lack of drive. These symptoms may be accompanied by reduced functioning, cognitive impairment, and altered behaviour (1), affecting the life and well-being of both patients and their relatives (2). In this study, we use the terms 'family' and 'relatives' to describe anyone who provides considerable and unpaid support to a person with a psychotic disorder. 'Family involvement' is an umbrella term that covers any systematic practice to include relatives in the assessment, treatment, and follow-up of the patient, but also efforts to address the needs of relatives themselves.

There is a continuum between basic family involvement practices and the more complex models that are referred to as family interventions (3). It is vital to establish contact and alliance with relatives, listen to their experiences and concerns, assess their strengths, limitations, burdens, and needs and provide them with general information about the illness, treatment, health services, and available support measures. Relatives may also provide clinicians with important collateral information, contribute to the development of a crisis/coping plan, and alert the health services when the patient's symptoms worsen. This basic level of family involvement and support is a necessary foundation for family interventions, which have become a pillar of the evidence-based treatment for psychotic disorders.

The various family interventions used in mental health care have much in common, even if based on different theoretical assumptions (4). The label 'Family psychoeducation' (FPE) is applied to a group of widely used and well-documented models that can be offered in a single- or multi-family format. These grew out of the realisation that schizophrenia is not caused by 'pathological' families, as was previously assumed. Rather, the high levels of 'expressed emotion' (EE) in some families, consisting of hostility, criticism, and emotional over-involvement, may reflect their attempt to deal with the patient's illness, often without sufficient knowledge, understanding, and coping skills (5). Evidence suggest that a high level of EE may further increase the risk of relapse, in accordance with the stress-diathesis model (6, 7). The FPE models target this vicious circle, by having clinicians provide both patient and relatives with emotional support, information concerning the illness and treatment, coping skills, recognition of warning signals, communication skills and structured problem-solving (5, 8).

Research shows that family interventions in general may improve the function, quality of life and adherence with treatment for persons with psychotic disorders, while also reducing the number of relapses and the number and length of hospital admissions (9–12). For relatives, these interventions may improve their experience of caregiving, their quality of life and the family function, as well as reduce their carer burden, distress and the level of EE (13–16).

The mediating factors and processes that generate these beneficial effects are of major interest, to identify core elements and improve the existing models (17). In this context, qualitative methods can be used to investigate the dynamics of family involvement to generate hypotheses for quantitative research. Some qualitative studies have explored the benefits and dynamics of FPE and similar models from patients and relatives' viewpoint (18–23), whereas studies on clinicians' experiences have largely focused on barriers and challenges (24, 25). In addition, qualitative studies have investigated basic family involvement practices as an integrated part of inpatient wards (26, 27), early intervention services (28, 29) and assertive outreach teams (30). However, there is a need for qualitative studies exploring how clinicians' perceive the utility and processes of FPE, as well as studies investigating combinations of basic family involvement practices and family interventions.

This qualitative study was nested in a cluster randomised trial, which purpose was to implement guidelines on family involvement for persons with psychotic disorders in Norwegian community mental health centres (CMHCs) (31). These national guidelines recommend both basic family involvement practices and family interventions (32, 33). A qualitative evaluation of the implementation process found that practicing family involvement was a major facilitator for implementation, since witnessing its benefits first-hand inspired the clinicians to continue (34). The present article follows up on this topic and aims to explore clinicians' perceptions of the utility of family involvement, including possible mediating factors and processes, by answering the following research question: how did mental health professionals experience using family involvement in the treatment of persons with psychotic disorders, in terms of perceived benefits and disadvantages for patients, relatives and clinicians?

2. Methods

This article is written in accordance with the 'Standards for Reporting Qualitative Research (SRQR)' (35) (Supplementary material 1).

2.1. Study design, context, and interventions

The cluster randomised 'Implementation of Family Involvement for persons with Psychotic disorders'—(IFIP) trial (31) took place in South-East Norway. Fourteen CMHC clusters were allocated to the experimental or control arm, whereupon the seven experimental clusters received an implementation support programme to implement national guidelines on family involvement from July 2019 to the end of 2020. The clinical units in both arms varied significantly in terms of size, geographical location, service type, and patient population (36). The study has been approved by the Norwegian regional committee for medical and health research ethics (REC) South-East with registration number 2018/128.

The Norwegian Directorate of Health has published national recommendations on family involvement and support in the health and care services, based on legal regulations, research evidence, ethical considerations, and discussions between key stakeholders and experts (33). These include general recommendations on identifying relatives, clarifying their role, and documenting the relevant information in the medical record, and further on how to involve relatives in the assessment, treatment, and follow-up of the patient, while supporting them during various phases of the patient's illness. The recommendations were condensed and operationalised as part of the IFIP project to produce a clinical intervention called 'Basic family involvement and support' (BFIS) (31). The Directorate of Health has also issued clinical practice guidelines that recommend FPE specifically in the treatment of psychotic disorders during all phases

of the illness (32). Consequently, the clinical interventions of the IFIP trial included both BFIS and FPE, which overlap to some extent (Table 1).

The IFIP trial employed multiple implementation strategies and interventions on both organisational and clinical levels. An important measure was the establishment of local implementation teams to plan and oversee the implementation effort. The teams usually included the local leader(s), an appointed family coordinator, one or more clinicians, and preferably also a user representative. One of the clusters in the experimental arm consisted of two clinical sites, each of which had its own implementation team. All clinicians in the experimental clusters were offered training and supervision in FPE and BFIS. They were encouraged to offer BFIS to all patients and their relatives, and FPE to as many of them as possible (37).

2.2. Sampling, participants and data collection

During the IFIP trial, implementation teams ($n = 8$) were interviewed two times, in the start and middle phases of the implementation period, whereas groups ($n = 5$) of ordinary clinicians were interviewed in the late phase. At three of the units, we chose to conduct focus groups with the implementation teams only, because these included a majority of the units' clinicians. For this particular study, the data material only included the second round of focus groups with the implementation teams, as well as the focus groups with ordinary clinicians, since implementation team members had not gained sufficient experience with the intervention in the early phase of the trial. Table 2 provides an overview of the participants.

The sampling strategy was purposive, aiming to interview clinicians who had practised systematic family involvement in the treatment of patients with psychotic disorders. We expected the implementation team members to be particularly dedicated and positive, whereas focus groups with ordinary clinicians could provide us with complementary and perhaps even critical perspectives. The latter were recruited through the local leaders according to our specific instructions: groups had to consist of 3–6 participants with various professional backgrounds, who could not be leader(s) or members of the implementation team. They must have practised family involvement for this particular patient group and at least one of them must have provided an entire course of FPE. We also encouraged the local leaders to include participants who were sceptical of, or less committed to, FPE or family involvement in general.

We obtained written informed consent from all participants before the start of each focus group. Using semi-structured interview guides (Supplementary material 2), most focus groups were carried out by two researchers visiting the site in question. Because of restrictions during the coronavirus pandemic, three of the focus groups were conducted with only one researcher being present. Participants were asked about the significance and utility of family involvement for the various stakeholders, including positive and negative experiences. They were also asked about ethical dilemmas and conflicts of interest, specifically concerning information sharing and confidentiality. Focus groups lasted for 60–90 min, were audio-recorded and transcribed verbatim. Recordings, transcriptions and field notes were stored in the University of Oslo's secure database (TSD). The resulting data material has previously been analysed to explore barriers and facilitators when implementing family involvement (34), as well as challenges related to confidentiality and information sharing (38).

2.3. Data analysis

Using a realist inductive approach to identify themes mainly at a semantic level, the first author employed Braun and Clarke's method for reflexive thematic analysis (39, 40). There were no strict criteria for

TABLE 1 Clinical interventions of the IFIP trial.

1. Basic family involvement and support	• At least three conversations about family involvement: one conversation with the patient alone, one with the relative(s) alone and one joint conversation
	• Written information about the family involvement at the unit, web resources and available support measures
	• Psychoeducative seminars for relatives
	• Developing a crisis/coping plan
2. Family psychoeducation (FPE) in single-family groups	• Engagement and alliance sessions
	• Warning signals, crisis/coping plan, genogram, goals of treatment
	• Psychoeducation
	• Communication skills exercises
	• Problem-solving sessions

TABLE 2 Overview of participants in focus groups with implementation teams and ordinary clinicians during the middle and late phases of the IFIP trial.

	Implementation team members		Ordinary clinicians	
	Middle phase of the trial		Late phase of the trial	
	January/February 2020 (*N*=39; 8 focus groups)		September/October 2020 (*N*=25; 5 focus groups)	
	N	%	*N*	%
Sex				
Male	5	13	5	20
Female	34	87	20	80
Age (years)				
20–35	5	13	7	28
36–50	16	41	11	44
51–70	18	46	7	28
Prof. background/role				
Section/unit manager	5	13		
Physician	3	8	4	16
Psychologist	5	13	16	64
Psychiatric nurse	15	38	1	4
Other	11	28	4	16

how frequent a pattern must be identified to constitute a theme. However, themes must be identified in focus groups with both implementation teams and ordinary clinicians, and must not be based solely on two focus groups from the same unit. All the data material was given equal attention in the coding process, but the analysis was focused and guided by the research question. The NVivo 12 software was used to store, organise, and code the data.

In addition to following the six phases described by Braun and Clarke (39), we added the following steps: the initial coding and thematic map was discussed with the co-authors to see if there were other ways of reading and interpreting the data. Preliminary themes and thematic maps were also discussed with the project's stakeholder committee, with valuable input both on themes that were already identified and on other possible themes. One of the co-authors simultaneously analysed interviews with patients, guided by a similar research question, and the results from both analyses were compared to look for similarities between clinicians and patients' perspectives. Thus, trustworthiness was enhanced by investigator triangulation (including both researchers and stakeholder representatives), and by data triangulation (including two kinds of focus groups with different participants in the analysis, as well as comparing the findings with those from interviews with patients). The results are presented below as a combination of condensed text and illustrative quotes.

2.4. Reflexivity

We are aware of the embedded and non-neutral position of all the authors of this article, as researchers who assisted and promoted the implementation of family involvement at the clinical sites where the participants worked. Consequently, we have strived to elicit critical perspectives in the focus groups and to provide a comprehensive account of clinicians' experiences.

3. Results

We identified four main themes that were categorised as perceived benefits (Figure 1): (1) Family psychoeducation—a concrete framework, (2) Reducing conflict and stress, (3) A triadic understanding, and (4) Being on the same team. Theme 1 described clinicians' overall perceptions of the FPE model and its structure, whereas themes 2–4 concerned the content, processes and utility of both BFIS and FPE, forming an interconnected triad of mutually reinforcing elements. Themes 2–4 were further linked to three important clinician-facilitated sub-themes: a space for relatives' experiences, emotions and needs; a space for patients and relatives to discuss sensitive topics and; an open line of communication between clinician and relative.

Concerning perceived disadvantages or challenges, we identified three main themes (Figure 2): (1) Family Psychoeducation—occasional poor model fit or difficulties following the framework, (2) Getting more involved than usual, and (3) Relatives as a potentially negative influence—important nonetheless. These themes were reported much less frequently than the perceived benefits. However, to provide a comprehensive account of clinicians' experiences, we have allowed their perceptions of disadvantages or challenges more space than their frequency would normally suggest.

Clinicians sometimes distinguished between BFIS and FPE, but usually shared their experiences of family involvement in general. The distinction is also blurred by the fact that they frequently used elements of FPE without offering the entire model, and that the initial phases of FPE are nearly identical to BFIS. When they attributed some benefit or disadvantage directly to either FPE or BFIS, we have emphasised this in our account. During the focus groups, clinicians used the terms 'family' and 'relative' broadly to refer to any significant person that had been involved in the assessment, treatment, and follow-up of the patient. There were no consistent thematic differences between the focus groups with implementation teams and those with ordinary clinicians. Illustrative quotes are labelled with 'FG' (Focus Group) followed by a number corresponding to a specific focus group.

3.1. Perceived benefits of family involvement

3.1.1. Family psychoeducation—a concrete framework

Clinicians were enthusiastic about offering a concrete and evidence-based intervention that is recommended in the clinical practice guidelines. Some reported an increased satisfaction with their clinical work, describing family involvement as both developing and meaningful. They further observed that relatives and patients appreciated being offered something concrete, structured and useful, which involved long-term cooperation. Clinicians frequently referred to the FPE model as a tool, or set of tools, where briefer versions or single elements could be employed in various therapeutical contexts. The elements, such as the problem-solving structure, could also be used by patients and relatives at home.

> **FG5:** 'I am in the middle of one (FPE) course, and then I have started one such «light version». And so, conversations with relatives is something I have always had, but now it is more systematised and I do feel that it is very nice to have something concrete, a tool. And then be able to refer to it, it is slightly easier then to sell it to both patient and relatives.'

The standardised length, content and sequence of elements was experienced as a useful aid by many clinicians, helping the groups return to a constructive process when sidetracked. They also saw that structure ensured predictability for patients, who may suffer from cognitive impairment. At the same time, clinicians considered the model flexible enough to accommodate different types of families and family dynamics.

> **FG6:** '(…) I experience that the tight structure, because there is room within the structure and… Right, to facilitate and also manage to deviate if there should be a reason for it, (…). And I am not afraid to do that, so I (…) also find that structure to be good. I see that for the patient it is important to be able to cope with being there.'

3.1.2. Reducing conflict and stress

An overarching theme was that family involvement seemed to reduce conflict and stress. The conflicts described were usually

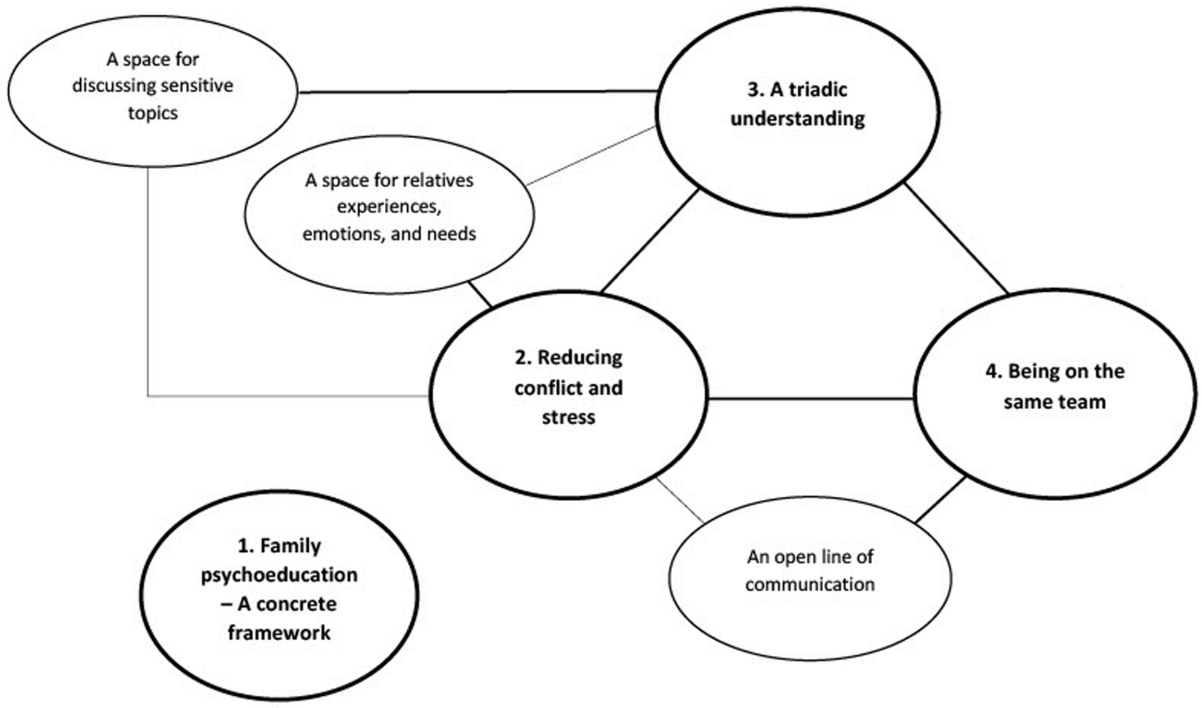

FIGURE 1
Thematic cluster 1: perceived benefits of family involvement, based on thematic analysis of focus groups with implementation team members and ordinary clinicians during the IFIP trial.

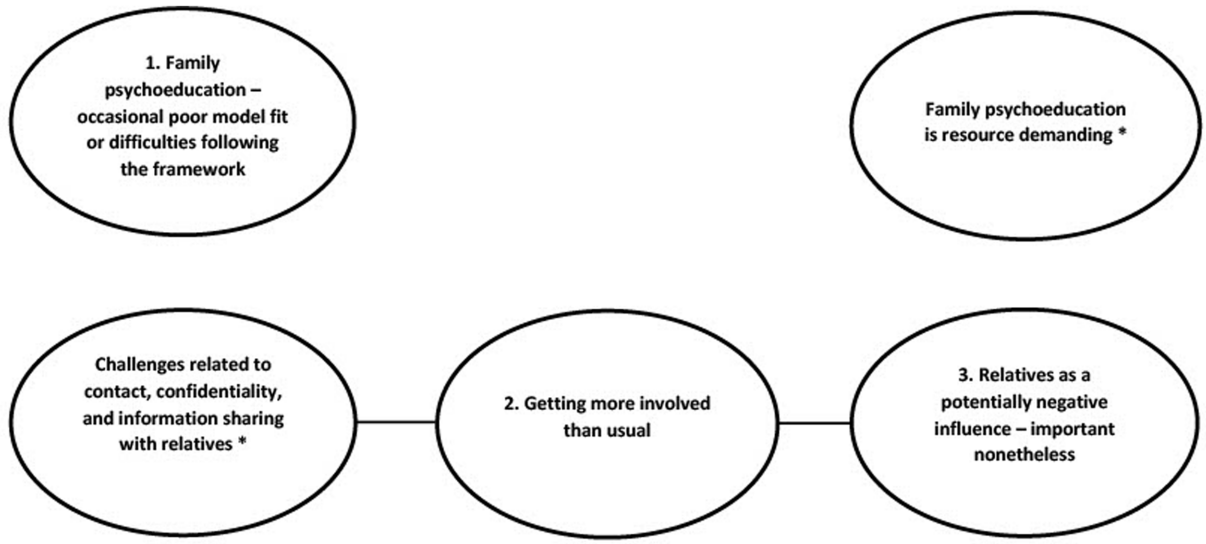

FIGURE 2
Thematic cluster 2: perceived disadvantages or challenges of family involvement, based on thematic analysis of focus groups with implementation team members and ordinary clinicians during the IFIP trial. *Main themes that have been analysed in previous articles.

between health personnel and relative(s) or between relative(s) and patient, while all stakeholders could experience stress. Conflict and/or stress often resulted from a lack of contact, cooperation and information exchange between relatives and health personnel, as well as a lack of openness and understanding between patient and relative. Family involvement, with the FPE model in particular, addressed these issues systematically and the results were described as 'lowered shoulders,' 'calmer relatives and home environment,' and 'reduced nagging and critical comments.' Clinicians further emphasised the utility of the 'communication rules' in FPE, and that family involvement could improve the communication between patient and relative(s).

An important sub-theme, linked to reducing conflict and stress, was to create a space for relatives' experiences, emotions and needs. Earlier when talking with relatives the focus was usually on obtaining collateral information, but now clinicians also asked them how the patient's illness affected their life and well-being. Relatives could 'ventilate' and articulate their frustration, without the patient being present and without clinicians judging them or defending the health services, but rather 'containing' their emotions by acknowledging and normalising them. This cathartic process appeared to greatly relieve their stress and reduce any resentment towards the health services, making it possible to start over and establish an alliance between clinicians and relatives. The alliance sessions in FPE emphasised this process specifically, but clinicians also reported using this competence outside the model. By focusing on relatives' experience, situation and needs it was easier to offer them adequate information, guidance and support.

> **FG7:** '(…) so a part of what I too experience that they (the relatives) appreciate is the validation of their own, what should I say, vulnerable topics. Things like one having done something wrong or that one is to blame for the patient becoming ill, and that they also get to hear that it is normal to have those thoughts, and receive psychoeducation about the illness (…) makes it easier for them to be relatives.'

> **FG11:** '(…) they (the relatives) seem more secure, that is (I) notice that, that relatives may not be as eager to make demands or require information, but get a sense of security in that, «yes we have a space where we get what we need». And that it also results in lowered stress for the patient.'

3.1.3. A triadic understanding

Clinicians observed that establishing contact and building an alliance with relatives, in addition to the patient-therapist alliance, opened up the possibility for a triadic understanding between clinician, patient and relative(s). The theme 'triadic understanding' includes an increased mutual understanding and acknowledgement, as well as a shared understanding. The latter term means sharing a platform of knowledge and concepts without necessarily agreeing on everything.

To create a space for discussing sensitive topics, characterised by trust, openness and a sense of equality between participants, was described as a critical foundation for a triadic understanding. It presupposed trust and alliance between all stakeholders, particularly between patient and clinician. Clinicians experienced that patient and relative(s) could discuss matters that were difficult to bring up in everyday conversation, perhaps because they were hard to articulate for the patient and/or were sources of conflict at home (such as substance abuse or negative symptoms). An important function of health personnel, referring to themselves in this context as 'diplomats,' was to put into words and explain to the relatives how the patient was feeling or experiencing the illness, on the patient's request.

> **FG1:** 'If for instance a boy/girlfriend comes along then, so even if they talk together a lot, they tend not to talk about the things that are important, and that it is good to just have that space. To talk, talk together and that the next of kin get to know a bit more.'

Clinicians emphasised that psychoeducation was a joint effort to establish a shared understanding, where they employed concepts, descriptions and illustrations from the FPE manual that patients and relatives could recognise as relevant to their experience.

> **FG10:** '(…) sometimes we asked (the patient), «Yes can you show us where you are on the didactic illustration? » And that is very good because then you speak the same language.'

A shared platform of knowledge and concepts, together with increased openness and a space to discuss sensitive topics, facilitated mutual understanding and acknowledgement. Clinicians observed that relatives gained an understanding of diagnosis and symptoms, particularly of negative symptoms, which further enabled them to understand and acknowledge the patient's situation better, adjust their expectations and reduce critical comments. In addition, clinicians provided relatives with guidance and concrete measures to handle challenging situations in a supportive way. Thus, anxiety, stress and conflict at home was reduced and relatives appeared more competent and secure to deal with illness-related issues.

> **FG7:** '(…) that the level of conflict within the family decreases. That it is both a question of solving various problems that often result in conflict, but perhaps in particular a different understanding of what is going on. That it is not a matter of laziness and things like that.'

> **FG3:** 'And understand (…) what they (the relatives)… What is sort of… Good things they can do themselves, when she is ill.'

Clinicians reported that relatives also gained an understanding of treatment, follow-up and prognosis, as well as the role of clinicians and the health services, which helped avert misunderstandings. Patients also seemed to appreciate relatives and clinicians' perspectives to a larger degree, although clinicians brought this up less frequently.

One of the most profound changes among clinicians was how they came to acknowledge relatives' situation and perspective through family involvement. This emerged as general reflections on relatives' burdens, needs and motivations, as well as accounts of specific experiences where family involvement provided such insights. In several instances, they related this phenomenon directly to the alliance sessions of FPE.

> **FG12:** 'I do think that the alliance sessions are gold in relation to us really wishing them (the relatives) well. Because they know that we have felt their pain. Each one. Because if you meet such a family, initially it may be so chaotic and so complicated. And so many ugly words or yelling or whatever. That makes it hard to, sort of, put up with it and think well of them. And I think that the alliance sessions affect us somehow. In the way we approach them. I think that with all the families I have worked with in that way, I have a completely different relationship than with other patients and their relatives.'

Family involvement gave clinicians increased access to collateral information, which contributed significantly to their understanding of the patient, in terms of clinical history, warning signals and the resources and capabilities that the patient had possessed before getting

ill. Clinicians also gained insight into the patient's context, including social relations and interactions, which afforded them a more holistic view of the patient.

> **FG13:** '(…) you do get, right (…) a different picture of the patient (…) that sorrow and joy of how life both was and how in a way life has changed (…) Because it, it has something to do with being able to perhaps see some other possibilities in the patient.'

3.1.4. Being on the same team

The final theme identified in 'the triad' was that family involvement generated a sense of 'being on the same team.' It meant acknowledging relatives as valuable partners and that clinical assessment, treatment and follow-up was a collaborative effort, where patient, relative(s) and clinician(s) pulled in the same direction as allies. Clinicians described this feeling of being on the same team as an antidote to the loneliness that both patient and relative may experience, in dealing with the illness on their own.

> **FG2**: '(…) and that they (the relatives) feel that they have a supportive role, that we are on the same team in a way. That everybody wants the best outcome, for instance not to have a new hospital admission (…), rather than it being «my responsibility, me alone, I am the one who is ill, I have to carry the burden», then it is more of a community around it.'

Clinicians recognised that it was vital to have an open line of communication, preferably by establishing contact with relatives early and in a calm phase, rather than late and during an acute crisis (which had been the norm). An open line meant that relatives had the possibility to contact clinicians directly for guidance and support, which appeared to reduce relatives' stress significantly. It could also mean that, with the patient's consent, clinicians would contact relatives for a mutual update, which increased the quality of follow-up.

> **FG4:** 'So what I like about it is that relatives have… Have an open line (of communication) with me. That I become a person who it is possible to reach without it… Without them having to jump through several hoops. To obtain special permits and such. One sort of gets that collaboration established and then it is there during a worse phase, then you sort of have a… A safety net (…).'

The quote above further illustrates how, by having an open line, relatives could perform an essential role as a safety net. With increased understanding of symptoms and warning signals, relatives were capable of detecting clinical deterioration earlier and alerting the health services, particularly when involved in critical treatment decisions and plans for crisis management.

3.2. Perceived disadvantages or challenges of family involvement

When asked directly about disadvantages or challenges of family involvement, many clinicians reported that they had experienced few or none. The three main themes in this section constitute a synthesis of the most frequently described disadvantages or challenges. However, clinicians did not always consider these challenges unequivocally negative when placed in their proper context. Two additional main themes were left out of this article due to potential overlap with previous publications. These were 'Challenges related to contact, confidentiality and information sharing with relatives' (38) and 'FPE is resource demanding' (34) (Figure 2).

In addition to the main themes, several codes were identified in only 1–2 focus groups, indicating a significant variety in the perception of and experiences with these challenges. Examples include that information could scare relatives or make them feel guilty, that clinicians were afraid of 'infantilising' the patient by involving relatives or that FPE, with its fixed schedule and communication rules, could be experienced as artificial or restrictive.

3.2.1. Family psychoeducation—occasional poor model fit or difficulties following the framework

Some clinicians reflected that the FPE model was most appropriate for younger and recently diagnosed patients, and that the training mainly focused on patients living with their parents. Although the model could address common reactions, issues and dysfunctional patterns in a family with a mentally ill person, there were also instances of poor model fit when the patient was too ill or the family conflicts too severe. In such cases, clinicians frequently described FPE as insufficient, and how following the structure could be difficult or unsuitable.

> **FG1:** '(…) That… They (the relatives) should have an increased understanding of (…) the patient. In FPE, the patient does have a bit… Yes, is in charge a little. In this particular case, I experience them as a deeply traumatised family after a lot of… Ehm… Problematic behaviour on the part of the patient. Where I feel that we fall short, with our current measures (FPE) (…).'

3.2.2. Getting more involved than usual

Clinicians recognised the benefits of creating a space for relatives' experiences, emotions and needs, as well as offering them adequate support. However, they also described how there was a thin line between this practice and becoming the relative's therapist. They sometimes struggled to determine the limits of their responsibility for relatives' health and well-being, particularly if the relatives were suffering from mental illness themselves.

> **FG3:** '(…) Because it has happened, that the patient was completely out of focus and it was all about mother's needs (…) Then you have to set limits and… Strict limits as well.'

Clinicians would also feel the despair, sorrow and pain of relatives more directly, with the risk of getting too emotionally involved and loosing professional distance. However, it was recognised as an unavoidable part of involving relatives and letting them share their experiences and emotions, and clinicians considered that the benefits outweighed this particular disadvantage.

> **FG6:** 'That is because the patient is so ill. And then there is also the fact that we, in such situations, may become co-sufferers. That we feel the emotional part, the despair and hopelessness that the family experiences and become slightly infected by it (…).'

The chance to observe social interactions within the family and to understand the patient's context was considered invaluable. However, with this position and knowledge clinicians also felt that the scope of their responsibility widened, and that they suddenly played a role in family dynamics.

> **FG8:** 'I think it is a dilemma (…) that we support the family, but perhaps what is needed is a separation. That is to say, the patient who is 34 years old has to move out soon maybe, and the dilemma is to what extent should we hold an opinion about that?'

3.2.3. Relatives as a potentially negative influence—important nonetheless

Clinicians described how relatives might constitute a negative influence on the patient in two main ways. Firstly, some relatives disagreed with clinicians about diagnosis and/or treatment, despite efforts to establish a shared understanding. Many went to file complaints against the services and clinicians were afraid that the relatives would sabotage the patient's treatment. They observed that adherence to treatment was often compromised when relatives were not onboard.

> **FG2:** '(…) And where the patient suffers and, or they are caught in between often, (…) I think many of them experience too (that) maybe we and (their) relatives disagree right. That relatives evaluate our treatment, medication, that it is not good, (it) does not help the trust and (therapeutic) relationship we are working on at the policlinic (…) Patients with psychosis do not tolerate it very well.'

However, clinicians did not consider that differing opinions was an argument against family involvement. On the contrary, it was important to explore their expectations and views through having contact.

Secondly, clinicians described how relatives might constitute a negative influence directly on the patient by being critical, overinvolved, neglectful or unable to understand despite participating in structured family involvement. An important realisation among several clinicians was that the family may not be ideal or even a particularly good influence, but it is still important to the patient. Consequently, family involvement is nearly always required to understand how the family works and help them adjust if possible or, as a last resort, help the patient to maintain some distance to the relatives.

> **FG5:** '(…) And I still have that thought in the back of my mind, that one grew up with this family and often perhaps they did not do the right things, but I have nonetheless adjusted my thoughts concerning the family. That is, the family is a part of, it may be a part of the problem, but at the same time it may be a part of the solution.'

4. Discussion

To the clinicians in this study, involving the family meant that patients were not alone in dealing with their illness, relatives were not alone with their burden and concerns, and clinicians were not alone in doing clinical assessments and follow-up.

Through their accounts, we see how the central benefits of family involvement in the treatment of psychotic disorders can be viewed as an interconnected triad. Reducing conflict and stress, a triadic understanding and being on the same team appeared to be mutually reinforcing themes in a continuous process. Furthermore, this triad of benefits was linked to three important clinician-facilitated sub-themes: a space for relatives' experiences, emotions and needs; a space for patients and relatives to discuss sensitive topics and; an open line of communication between clinician and relative to ensure appropriate follow-up and continuous support.

4.1. Perceived benefits of family involvement

As mentioned previously, qualitative studies on clinicians' perceptions of FPE and similar interventions have mainly focused on barriers and challenges. However, consistent with our findings, they also report that health professionals generally consider the framework and tools useful, while emphasising the need for flexible adaptations (24, 25, 41).

Some qualitative studies have investigated patients and relatives' perspectives on FPE and similar interventions in single- and/or multi-family formats. These often emphasise how improved communication and a reframing of relatives understanding leads to a reduction in conflict and stress (18, 19, 21). Their findings resonate well with the perceived benefits and processes identified in our study, and are consistent with the theory that FPE generates a reframing of relatives understanding, which through a reduction in the level of EE leads to reduced relapse rates (17). The clinicians in our study emphasised how negative symptoms were particularly hard for the relatives to identify as being part of the illness, and thus vital to address in order to achieve this reframing. They also reported that increased understanding among relatives might lead to better monitoring and follow-up of the patient.

Qualitative studies of family interventions have also described increased mutual understanding within the family, as well as increased family cohesion and unity among some participants (22, 23). However, a contribution of this study is to describe how mutual understanding and acknowledgement between all three stakeholders may increase during family involvement. Our findings also suggest that a shared understanding, of illness-related concepts and processes, is linked to increased mutual understanding and acknowledgement through a mutually reinforcing process. We therefore use the term 'a triadic understanding' to describe both shared and mutual understandings and their reciprocal connections.

A triadic understanding may be accompanied by a sense of 'being on the same team.' Previous qualitative studies of multi-family interventions have emphasised the importance of peer support and a sense of belonging (19, 20, 22). Still, our data indicate that a reduced feeling of loneliness, as well as an increased sense of belonging and inclusion, may be important mediators of single-family interventions as well. Qualitative studies of general family involvement in mental health care have described how clinicians may consider relatives valuable partners, teaming up with them to provide the patient with the best possible care (28, 42–45). Yet our

findings demonstrate how clinicians may expand the concept of 'being on the same team' to include the patient as well.

The FPE and BFIS models may provide clinicians, relatives and patients with a basis for achieving this triad of benefits together, but through clinicians' accounts we may also recognise their critical role in this process. Creating a space for relatives' experiences, emotions and needs; a space for patients and relatives to discuss sensitive topics and; an open line of communication between clinician and relative, may be regarded as important clinician-facilitated elements to establish and maintain successful family involvement. These sub-themes were directly linked to a reduction in conflict and stress during all phases of family involvement, by our participants. Qualitative studies of general family involvement in mental health care also emphasise that relatives should be offered a space by themselves to share their experiences, emotions and needs (26, 28, 45–47), as well as the importance of having an open line of communication to ensure continuous support, appropriate follow-up and enabling relatives to act as a safety net (28–30, 43–45). However, perhaps the most prominent theme in qualitative research on family involvement is how it leads to increased understanding and acknowledgement, when there is a space to share experiences and discuss sensitive topics, characterised by openness, trust and support. This appears to be the case, regardless of whether researchers have explored family involvement in general or specific interventions, whether it was offered in single- or multi-family format and whether it was grounded in a biopsychosocial or postmodern ethos (18, 19, 22, 23, 27, 44, 46, 48, 49). A recent review (17) similarly found that common therapeutic factors—therapeutic alliance, support and the opportunity for sharing—might contribute significantly to the effects of family interventions, in a manner already recognised in psychotherapy research.

4.2. Perceived disadvantages or challenges of family involvement

To succeed with the implementation of family involvement in mental health care, it is vital to acknowledge the disadvantages or challenges that clinicians may experience. In the IFIP trial, lack of shared perceptions, competence, routines, resources and uncertainty regarding the engagement phase and confidentiality were identified as major barriers (34, 38). The present study however, looked at perceived disadvantages or challenges in clinical practice when family involvement actually takes place.

Clinicians reported disadvantages or challenges less frequently, and with a larger variety, than they described the benefits of family involvement. This might indicate that random factors related to particular patients, families, sites or clinicians, rather than family involvement itself, could explain some of the challenges.

The fact that the FPE model and its structure does not fit every client and relative is generally recognised (25). However, it is interesting that clinicians with extensive experience with FPE seem to consider that there is poor model fit for some patients or families (25, 41), while clinicians in a study who received training but did not practise FPE considered the model to be unfit for most of their patients (24). This may corroborate the findings of a previous article from the IFIP trial, which showed that practicing family involvement and experiencing its utility first-hand, for all stakeholders in various situations, is important for clinicians to overcome central barriers (34).

The challenges with getting more involved than usual were described as inevitable by clinicians, who in general considered the benefits to outweigh the disadvantages. However, a prominent finding was that they were conscious not to become the relative's therapist, a notion that has been reported in previous studies (42, 50). This dilemma perhaps exemplifies a more general problem in the health and care services, which is the uncertainty as to who should look after relatives' health and well-being. It may also reflect how the education of health professionals in Norway has traditionally focused on the patient, without adequately emphasising the importance of relatives and the patient's social network.

Finally, we see how clinicians realised that family involvement was nearly always required and useful. If relatives disagreed with the diagnosis or treatment, or if they constituted a potentially negative influence on the patient in other ways, it was necessary to uncover this through family involvement and act accordingly. This constituted a major shift in clinicians' attitudes, from primarily focusing on disadvantages and barriers to recognising these obstacles but emphasising solutions and benefits instead (34).

4.3. Strengths and limitations

Being nested in a successful implementation trial (37), the present study is in a unique position to explore how clinicians perceive the benefits of family involvement when major barriers to implementation on both organisational and clinical levels have been traversed (34, 51, 52). Similarly, it can give an outline of the disadvantages or challenges that clinicians nonetheless experience.

Many of the perceived benefits and processes identified in the present article have been described in previous qualitative studies on patients and relatives' perspectives, which may corroborate our findings. This study is also likely the first to explore all of these perceived benefits together and to place them in a thematic 'system' according to the processes described by clinicians. It is probably made possible by two main factors. Firstly, implementing BFIS together with FPE makes this study uniquely placed to explore the dynamics between basic and complex forms of family involvement. However, it also means that it cannot be regarded as a 'pure' exploration of the mediating factors of the FPE model.

Secondly, by focusing on clinicians' perspectives we get a 'bird's-eye view' of benefits for both patients, relatives and clinicians, with certain limitations. Unlike previous studies on patients' perspectives for instance, the clinicians in our study did not emphasise increased coping skills (22), personal responsibility or independence (18, 23) for the patient. Another example concerns the theme 'a triadic understanding,' where clinicians were less concerned with patients understanding relatives better. However, we know from the analysis of interviews with patients that understanding relatives' perspective and situation was an important part of their experience (Hansson et al., submitted). It shows how perspectives from patients and

relatives are needed to complement the findings, which is why the IFIP trial conducted qualitative studies on relatives and patients' experiences as well.

Clinicians did not report their experiences unfiltered and their narratives might be shaped by their training and knowledge of how the FPE model is supposed to work. Similarly, the normative position and theoretical knowledge of the researchers might have influenced the interpretation of clinicians' accounts, possibly adding a second layer of confirmation bias. It is possible that focus groups with clinicians in the control arm or in units that refused to participate would have provided us with other perspectives. Although we strived to include critical voices in this study, it is possible that 'dissidents' did not participate, either through their own choice or the local manager's decision. Even if they did participate, it is possible that they did not feel able to speak their mind freely in front of colleagues and researchers. This also points to a general limitation of the focus group format.

The topics discussed in this study concern the relationships and dynamics between elements of family involvement and observed benefits or disadvantages, but the qualitative methodology is not suitable to investigate causality. We must therefore regard this as an explorative study that may generate hypotheses for quantitative research. In terms of external validity, our study took place in a specific geographical, clinical and cultural context, and focused only on family involvement for persons with psychotic disorders. However, there is increasing evidence that these interventions are relevant to other patient groups (53, 54), as well as in other sociocultural contexts (55).

4.4. Implications

Our findings might indicate that implementing BFIS and FPE together may be particularly advantageous. They further seem to warrant a particular emphasis on negative symptoms during psychoeducation and an increased awareness of the important clinician-facilitated elements during all phases of family involvement. Perceived disadvantages or challenges should be acknowledged and addressed in future implementation efforts and research.

5. Conclusion

This nested qualitative study showed how clinicians mainly reported positive experiences with family involvement in the treatment of psychotic disorders. The FPE model and framework was experienced as particularly useful. Family involvement led to a 'triad' of perceived benefits: reducing conflict and stress, a triadic understanding and being on the same team. Clinicians further facilitated this triad of benefits by creating a space for relatives' experiences, emotions and needs, a space for relatives and patients to discuss sensitive topics and an open line of communication with relatives to provide continuous guidance and support. The challenges described were occasional poor model fit, being involved more than usual and that relatives might constitute a negative influence on the patient. Our findings could be used to inform clinical practice, as well as future quantitative research on mediating factors and implementation efforts.

Data availability statement

The datasets used and/or analysed during the current study are not available, since the participants of this study did not give written consent for their data to be shared publicly.

Ethics statement

The studies involving human participants were reviewed and approved by the Norwegian Regional Committee for medical and health research ethics (REC) South-East, registration number 2018/128. The patients/participants provided their written informed consent to participate in this study.

Author contributions

All authors made significant contributions to the conception and design of the study, with particularly substantial contributions from KSH and RP. MR did a preliminary mapping of the participating units' structure, organisation and practice, and made substantial efforts to recruit clinical units with aid from the other authors. Data collection was performed by all the authors. Analysis was mainly carried out by LH, with assistance from RP, MR, and KMH. LH wrote the first draft of this article. All the authors critically revised the article, gave their final approval before submission, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2023.1175557/full#supplementary-material

SUPPLEMENTARY DATA SHEET 1
SRQR checklist.

SUPPLEMENTARY DATA SHEET 2
Interview guides.

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