Mental health problems in Norwegian general practice. Identification, presentation, and diagnosis

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The rationale for this thesis

Mental health disorders are common and pose a significant burden on people's lives. Most patients are treated in primary care, often by their general practitioner (GP). The workload of GPs is under pressure, and there is an ongoing GP crisis in several countries, including Norway. This threatens the GP's capacity to provide the necessary care for patients suffering from mental health disorders.

Studies have indicated that GPs do not adequately identify and diagnose mental health disorders. However, this is a complex issue. For example, many patients who contact primary care will have passing symptoms not compatible with a mental health disorder. In addition, physical and somatic symptoms often overlap in general practice, and mental distress can be difficult to distinguish from other somatic presentations of physical illnesses and other health complaints.

There is an ongoing discussion concerning the extent to which current classification systems are valid in diagnosing mental health disorders in general practice and the complex interrelation between mental and physical symptoms and diseases as they present themselves in primary care.

A diagnosis is of significance to a patient receiving it and a prerequisite for treatment, including medication and referral to specialized health care services. It is also a prerequisite for welfare rights such as sickness leave and disability benefits.

The importance of adequate diagnosis of mental health disorders in primary care dictates the need for research from general practice on the presentation and diagnosis of mental health disorders. This will contribute to the knowledge necessary to provide high-quality primary care for patients struggling with mental health problems in general practice, thereby increasing the probability of positive outcomes.

Preface

I was first introduced to my professors and later supervisors Mette Brekke and Ole Rikard Haavet as a medical student. As part of our student curriculum, we were placed for six weeks at a GP office, and I was deployed at the office of Mette Brekke. This placement gave me an insight into everyday life in general practice, and I was impressed at how elegantly Mette was balancing all the different patients and clinical queries she encountered during her day. This appeared very different from what I had experienced as a medical student in hospital settings thus far.

At the time, I was working as a research assistant on the Autism Birth Cohort study at the Institute of Public Health (FHI) in Oslo, and I was set to write my student thesis there. However, despite this already positive grounding, I was so intrigued by the student placement that I asked Mette about the possibility of writing my student thesis from the Department of General Practice instead. She referred me to Ole Rikard Haavet, and he agreed to be my student supervisor.

I ended up undertaking a small qualitative study on adolescents' perceptions of health and help-seeking for mental health issues. I found this task very interesting, especially since the adolescents I interviewed gave different answers than expected. Positive social connections with family and friends were the most important factors for good health, they told me. And having a trusting relationship with a healthcare provider was necessary before disclosing mental health issues and asking for help. These results surprised me, and it was a little intriguing to have one's premonitions turned. Having thought they would talk about physical fitness and body image, this was barely mentioned. Safe to say, it was motivating for further academic work. And even though I may have struggled through a bit, Ole Rikard's patience and calm confidence that I would eventually make it through surprised me again. What was it about these GPs? And GP professors?

Despite my trials and tribulations in my student thesis, the results ended with a publication in a scientific journal. A few years later, as a fresh intern in Finnskogen, Ole Rikard called and asked me if I would be interested in doing a PhD. He was engaged in a research project. This project was a collaboration between the Department of General Practice at the University of Oslo and the Division of Psychiatry at Akershus University Hospital, led by Professor Torleif Ruud. I was eventually included in our main research project titled “Shared Care and Usual Health Care for Mental and Comorbid Health Problems”, a project then only in its planning stages.

I entered a multidisciplinary group with researchers from general practice, psychiatry, sociology, psychology, health economy, and health services research. I was surrounded by a lot of experienced colleagues, and I was able to participate in the planning and implementation of a large cluster-randomized trial. As the first PhD candidate in the group, I was assigned baseline data, which means purely observational data from before the intervention began.

I was given a lot of freedom to define and shape the articles I wanted with the data available to me. As a result, my focus gradually moved from health services towards what I encountered as a medical student and later as an intern in general practice: That patients present with health concerns for which there is not always a simple answer, that mental distress is commonly a part of the picture, and most symptoms are part of a larger, more complex circumstance and context.

Now that I am at the tail-end, I can look back on a long and instructive process. I have been given time and space to settle into academic research. I have been challenged and supported but mostly given a lot of freedom. It has been an interesting journey, and I am curious to see what’s next.

Acknowledgements

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I want to thank Grorud legesenter, Haugerud legekontor, Høybråten legekontor, Kalbakken legegruppe, Trygg Helse legesenter and Stovner legesenter for their collaboration, and my appreciation to all the participants for their contributions.

I want to thank the members of my research group at the Division of Mental Health Services at Akershus University Hospital for their collaboration in our main research project: Jorun Rugkåsa, Ajmal Hussain, Ole Gunnar Tveit, Julie Berteig, Inger Cathrine Kann, Ketil Hanssen-Bauer, Svein Gjelstad, Ole Rikard Haavet, Eirik Bjelland and Torleif Ruud.

My warmest appreciation for the guidance of my supervisors: My main supervisor Professor Mette Brekke, and my co-supervisors, Professor Emeritus Ole Rikard Haavet and Professor Emeritus Torleif Ruud. They are calm, collected, and wise. I am forever indebted to Ole Rikard Haavet for providing this opportunity, as I would never have thought to pursue this direction otherwise. And thank you, Mette, for guiding me through.

I want to thank all my colleagues for their support along the way. I want to thank Professor Bård Natvig for undertaking my midway evaluation. Warmest thanks to Ibrahimu Mdala for his invaluable help performing the statistical analyses. You are patient and a good teacher. You make complex concepts easy(er) to understand.

I want to thank Jurate Šaltytė-Benth for her participation in our second article, providing her help and expert experience to ensure our analyses were conducted at the level of detail I was aiming for.

I want to thank my fellow PhD-candidates in the department, all of us trying to find our way through the maze and keeping good company along the way. A special thanks to Tonje Rambøll Johannesen for her wit and logical thinking that have got me through many dark and stormy nights in the process. I also want to thank Ellen Wikenius for her support through the early years of this work and for introducing me to my canine research companion, Marley.

Combining academic work with the concrete dealings at Moss emergency primary care centre has been an invaluable combination throughout these years. I am so thankful for the splendid colleagues I have spent many memorable nights with at the front lines, caring for patients and dealing with the largest to the smallest aspects of all things imaginable.

Lastly, I am forever grateful to the people closest to me.

You know who you are.

Hurum, October 2022

Mina Piiksi Dahli

Summary

Background

Mental health disorders are common and significantly burden patients' health, healthcare systems and society in general, and patients are primarily cared for in general practice. Patients with mental health disorders have more somatic health problems than those without mental health disorders and often only present with somatic symptoms when visiting their GP. This may challenge the identification and diagnosis of mental distress and mental health disorders. Studies have pointed towards GPs' not recognising mental health disorders in their patients. Still, diagnosing mental health problems in general practice is a complex issue. It is unclear how well the current approach and diagnostic systems address the complexities of mental health problems as they present in primary care.

Aim

This thesis aims to explore mental health problems in general practice by studying the prevalence and distribution of patients with psychological diagnoses, their related frequency of consultations, the association between psychological diagnoses and different somatic symptom diagnoses, and whether GPs diagnoses correspond with patient-reported levels of mental distress.

Methods

We performed cross-sectional analyses of electronic medical records from a cohort of all registered contacts of patients aged 16-65 during 12 months in 2014-2015. This included 16,845 patients with a total of 68 814 consultations in six GP office centres with 35 GP practices in Oslo, Norway. The variables extracted were age, sex, type of contact, GP code, and ICPC-2 diagnostic codes. We also performed a questionnaire

study with 553 patients aged 16-65 who entered these six office centres for two weeks in 2015. The questionnaire comprised CORE-10, which measures general mental distress. We gathered electronic medical records for these 553 patients nine months from when the questionnaire study was performed. We performed cross-sectional analyses from the questionnaire study coupled with clinical cohort data. We used descriptive comparative designs to study associations and differences between groups.

Results

In total, 18.8 % of patients received one or more psychological (P) diagnoses during the 12 months. Of these, 48.4 % received a diagnosis from the symptom categories of ICPC-2, 37.0 % from the disorder categories, and 14.5 % of patients received both. Depression was most common, accounting for 27.9 % of the diagnosis, followed by acute stress reaction at 14.9 %, anxiety at 13.5 %, and sleep disturbance at 10.8 % of the total P-diagnoses. Patients with a P-diagnosis had a significant increase in consultations ($p<0.001$), with a mean of 6.4 versus 3.5 for patients without P-diagnoses.

Patients with depression, anxiety or stress-related diagnoses had a significant increase in somatic symptom diagnoses with a mean (SD) of 2.9 ± 3.6, compared to 1.9 ± 2.5 for patients without any P-diagnoses during the 12 months ($p<0.001$). We found a significant increase in somatic symptom diagnosis for each of the individual P-diagnoses viewed separately for both sexes and most age groups. The probability of a P-diagnosis increased significantly ($p<0.001$) with an increasing number of somatic symptoms diagnoses received during the 12 months. The symptom diagnoses most strongly associated with having a P-diagnosis were general weakness/tiredness, stomach pain, palpitations, musculoskeletal pain, headache, dizziness, incontinence, constipation, and irregular menstruation.

We found that 73.3 % of patients with high levels of self-reported mental distress versus only 13.3 % of patients with low levels of mental distress had received a P-

diagnosis ($p<0.01$). We found a significant difference in the number of consultations ($p<0.01$), with a mean of 15.9 consultations for patients with high levels of distress versus a 9.1 mean number of consultations for patients with low scores for mental distress during the 21-month cohort period, regardless of having a P-diagnosis. We found that each unit increase in CORE-10 score and each additional consultation increased the likelihood of having a psychological diagnosis by 17 % (OR 1.17) and 7 % (OR 1.07), respectively.

Conclusions

Nearly one in five patients had received a psychological diagnosis in our material. Depression and anxiety were the most common, followed by acute stress reaction and insomnia. Patients with psychological diagnoses have more consultations with their GP regardless of age, sex, and reason for contact. Patients with anxiety, depression, and stress-related diagnoses have a higher number of somatic symptom diagnoses than patients without any P-diagnoses, also viewed separately and for both sexes and most age groups. There was a clear association between patients' level of mental distress and having received a P-diagnosis in the material. The probability of a P-diagnosis increased with increasing levels of mental distress and an increasing number of consultations. Still, only around 75 % of patients with high levels of mental distress had been recognized with a P-diagnosis.

Sammendrag

Bakgrunn

Psykiske lidelser er utbredt i befolkningen, og medfører en stor belastning på pasienters helse og samfunnet generelt. Pasienter med psykiske lidelser behandles hovedsakelig i primærhelsetjenesten. Man har sett en økt forekomst av fysisk helseplager for pasienter med psykiske lidelser, og mange presenterer kun sine fysiske helseplager når de møter hos allmennlegen. Dette kan medføre utfordringer i korrekt identifisering og diagnostisering av psykiske lidelser. Flere studier har pekt mot allmennlegers begrensede evne til å identifisere pasienter med psykiske helseplager. Diagnostikk av psykiske helseplager i allmennpraksis en kompleks problemstilling, og det er uklart i hvilken grad dagens tilnærming og dagens diagnostiske systemer adresserer de komplekse kombinasjonene av fysiske, psykiske og sammensatte lidelser slik de presenterer seg i allmennpraksis.

Formål

Formålet med denne avhandlingen er å utforske psykiske problemstillinger i allmennpraksis ved å studere forekomst av ulike psykiske diagnoser, hyppighet av kontakt, hvordan psykiske diagnoser er assosiert med fysiske symptomdiagnoser, og hvorvidt allmennlegers diagnoser samsvarer med pasientrapporterte psykiske plager.

Metode

Vi utførte deskriptive og komparative tverrsnittsanalyser fra en kohort bestående av elektroniske journaldata fra alle pasienter i alderen 16-65 år som møtte hos fastlegen i løpet av 12 måneder ved seks legekontor og 35 legepraksiser i 2014-2015. Dette inkluderte totalt 16 845 pasienter med totalt 68 814 konsultasjoner. Uthentede variabler inkluderte: Alder, kjønn, kontakttype, legekode og ICPC-2 diagnosekoder per kontakt. Vi gjennomførte i tillegg en spørreskjemaundersøkelse med totalt 553 pasienter som møtte på de inkluderte legekontorene i løpet av to uker i 2015.

Spørreskjemaet inkluderte CORE-10, et validert screeningverktøy for generelle psykiske plager. Vi innhentet elektroniske journaldata for disse 553 pasientene for ytterligere ni måneder fra undersøkelsen ble gjennomført. Vi utførte tverrsnittsanalyser fra spørreskjemaundersøkelsen kombinert med kohortdata, med et deskriptivt komparativt design for å studere assosiasjoner og forskjeller mellom grupper.

Resultater

Totalt 18.8 % av pasientene hadde fått en eller flere psykiske diagnoser i løpet av de 12 månedene. Av disse hadde 48.4 % kun fått en symptomdiagnose, 37.0 % en sykdomsdiagnose og 14.5 % av pasientene hadde begge deler. Depresjon var den største gruppen med 27.9 %, etterfulgt av akutt stressreaksjon med 14.9 %, angstlidelser med 13.5 % og søvnvansker med 10.8 % av totalt antall psykiske diagnoser i materialet. Pasienter med psykisk diagnose hadde en signifikant økning i antallet konsultasjoner hos legen ($p<0.001$) med et gjennomsnitt på 6.4 konsultasjoner versus 3.5 for pasienter uten psykiske diagnoser.

Pasienter med depresjon, angst, akutt stress eller PTSD diagnose hadde et signifikant økt antall fysiske symptomdiagnoser med et gjennomsnitt (SD) på 2.9 (3.6) versus 1.9 (2.5) for pasienter uten psykiske diagnoser. Vi fant en signifikant økning også når vi studerte de psykiske diagnosene hver for seg, inkludert begge kjønn og de fleste aldersgrupper. Sannsynligheten for å ha fått en psykisk diagnose økte signifikant ($p<0.001$) med økende antall symptomdiagnoser i perioden. Enkeltdiagnoser som var sterkest assosiert med en psykisk diagnose var; tretthet, svimmelhet, dyspné, hodepine, magesmerter, hjertebank, muskel/skjelettsmerter, urininkontinens, forstoppelse og uregelmessig menstruasjon.

Totalt 74.3 % av pasienter som rapporterte uttalte psykiske plager hadde fått en psykisk diagnose hos legen, sammenliknet med 13.3 % av pasienter som rapporterte lave nivåer av psykiske plager. Sannsynligheten for en psykisk diagnose økte med økende nivå av psykiske plager (p<0.01) og økende antall konsultasjoner (p<0.01). Pasienter med uttalte psykiske plager hadde et signifikant økt antall konsultasjoner med legen i løpet av 21 måneder, uavhengig av om de hadde fått noen psykisk diagnose, med et gjennomsnitt på 15.9 versus 9.1 for pasienter med lite psykiske plager. Hver økning i sum på skåringskjema for psykiske plager, og hver økning i antall konsultasjoner hos legen, økte sannsynligheten for å ha fått en psykisk diagnose med henholdsvis 17 % (OR 1.17) og 7 % (OR 1.07).

Konklusjon

Nær en av fem pasienter hadde fått en psykisk diagnose i vårt materiale. Angst og depresjon var de hyppigst forekommende, etterfulgt av akutt stressreaksjon og søvnvansker. Pasienter med psykiske diagnoser hadde en signifikant økning i antall konsultasjoner sammenliknet med pasienter uten noen psykisk diagnose, uavhengig av alder, kjønn og årsak til kontakt. Pasienter med angst, depresjon eller stressrelaterte diagnoser hadde en signifikant økning i antall somatiske symptomdiagnoser, både samlet og ved hver enkelt diagnose analysert for seg. Det gjaldt begge kjønn og de fleste aldersgrupper. Pasienter med høyt nivå av psykiske plager hadde en signifikant høyere sannsynlighet for å ha fått en psykisk diagnose hos legen, og sannsynligheten for å bli identifisert med en slik diagnose økte med økt antall konsultasjoner og økende nivå av psykiske plager. Pasienter med høyt nivå av psykiske plager hadde økt antall konsultasjoner med lege uavhengig av om de var blitt identifisert med en psykisk diagnose.

List of papers

I. **Prevalence and distribution of psychological diagnoses and related frequency of consultations in Norwegian urban general practice**
Dahli M, Brekke M, Ruud T, Haavet OR
Scandinavian Journal of Primary Health Care 2020 38 (2), 124-131
DOI: https://doi.org/10.1080/02813432.2020.1783477

II. **Somatic symptoms and associations with common psychological diagnoses: a retrospective cohort study from Norwegian urban general practice**
Dahli M, Šaltytė-Benth J, Haavet OR, Ruud T, Brekke M
Family Practice 2021 Nov 24;38(6):766-772
DOI: https://doi.org/10.1093/fampra/cmab038

III. **GPs' identification of patients with mental distress: a coupled questionnaire and cohort study from Norwegian urban general practice**
Dahli M, Haavet OR, Ruud T, Brekke M
BMC Primary Care 2022 23, 260
DOI: https://doi.org/10.1186/s12875-022-01865-x

Definitions

- **Somatic symptom diagnoses:** Diagnostic codes from the 00-29 parts of the different organ chapters in ICPC-2
- **Mental health problems:** A term that covers all mental health-related problems, both mental distress, symptoms, and mental health disorders
- **Mental distress:** Symptoms and experiences of a person’s inner life commonly held to be troubling, confusing, or out of the ordinary. Not related to any medical diagnosis
- **Mental health disorder:** A behavioural or mental pattern that causes significant distress or impairment of personal functioning, qualifying for a medical diagnosis according to a diagnostic classification system
- **Mental illness:** General term covering mental health distress, symptom experience and diagnosable mental health disorders
- **Psychological diagnosis:** Diagnostic codes from the psychological (P) chapter in ICPC-2

Abbreviations

CORE-10	Clinical Outcomes in Routine Evaluation Questionnaire
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders v. 4
EMR	Electronic medical records
FA	Frequent attender
GP	General practitioner
ICD-10	International Classification of Diseases v. 10
ICPC-2	The International Classification of Primary Care (ICPC) v. 2
MUS	Medically unexplained symptoms
OR	Odds ratio
P-diagnosis	A diagnosis from the psychological (P) chapter of ICPC-2
REK	Regional Committee for Medical and Health Research Ethics
RGP	Regular general practitioner
SD	Standard deviation
SSD	Somatic symptom diagnosis
WHO	World Health Organization
WONCA	World Organization of Family Doctors
WPA	World Psychiatric Association

1 Background

1.1 Mental health disorders

"Virtually all of our measures of "psychopathology" are built on the assumption that to be psychologically healthy is to be free of disordered emotional and cognitive responses. According to this standard, a coma victim might be considered the ideal of psychological health."

Steven C Hayes et al. (1)

1.1.1 Defining mental health disorders

Like most things in medicine, we conceptualize mental health on a spectrum: from 'healthy' to 'sick'. Exploring the existential aspects of our mental health is outside the scope of this thesis. Still, it is essential to note that the definitions of what constitutes mental illness are dynamic and have changed over time (2). There is still no general consensus on the definition of a 'mental health disorder' (3).

The World Health Organization (WHO) describes mental health as "a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community" (4). They describe mental health disorders as "characterized by a clinically significant disturbance in an individual's cognition, emotional regulation, or behaviour" (5).

The diagnostic classification system used in Norwegian general practice today is ICPC-2 (The International Classification of Primary Care version 2), developed by WONCA (World Organization of Family Doctors) (6). The classification system used in specialized health care is ICD-10 (International Classification of Diagnoses and

Related Health Problems 10th version) (7). ICD-10 was adopted by WHO in 1990 and implemented as the official Norwegian classification of mental health disorders in 1997 (8). WHO has developed an eleventh version, ICD-11, which was approved in 2019 but is still not implemented in Norway (9). WHO has also published more detailed descriptions of the criteria for making a specific mental health diagnosis in ICD-10 (10, 11). These specifications made ICD-10 closer in structure to the Diagnostic and Statistical Manual of Mental Disorders, DSM-V, another classification system in wide use (12).

These diagnostic systems define what constitutes a mental health disorder in the health care system today. A diagnosis is a precondition for prescribing pharmacological therapy and other forms of treatments and for referral to specialist care. Diagnoses also dictate the basis for welfare benefits, such as sickness and disability benefits from the state. However, there is an ongoing discussion of whether current diagnostic systems adequately capture mental health problems as it presents in primary care, both from psychiatry (13, 14) and general practice (15-17).

1.1.2 Prevalence and impact of mental health disorders

Mental health disorders are among the most common health disorders worldwide (18). A systematic review of the global prevalence of mental health disorders from 2014 found that approximately one in five (17 %) would be identified as having a common mental health disorder during a year and one in three (29 %) at some time during their lifetime (18). A German critical review from 2005 estimated that 27 % of the EU population each year suffers from a mental health disorder. About one-third had more than one disorder, indicating considerable comorbidity. The most common disorders found were anxiety, depression, somatoform, and substance abuse disorders (19). An updated review from 2011 found that 38.2 % of the EU population suffers a mental health disorder each year. This study included neurological disorders in children and the elderly (20). Mental health disorders significantly burden individuals, families, and societies (21, 22). Patients with mental health disorders have lower life quality, poorer health and a lower life expectancy compared to the general population (22-27).

A report from the Norwegian Institute of Public Health from 2018 estimated that around 16-22 % of the adult population satisfy the criteria for at least one mental health disorder each year, the most common being anxiety, depression and substance abuse disorders (28). In a country with widespread access to primary care, the prevalence of mental health problems in general practice could be expected to mirror the level existing in the general population (29). Even so, many who suffer from mental health disorders either do not contact health services or are not identified with their mental health problem (30-32).

1.1.3 Prevalence of mental health disorders in general practice

There are different approaches in the literature to studying the prevalence of mental health disorders in general practice. Most studies are based on clinical interviews of patients using different screening tools (33-41) or patient-administered questionnaires (42-47). Some studies extract data from electronic medical records (EMR) (48, 49) and some from primary care registry data (50, 51). Different studies report diagnoses from the different diagnostic classification systems in use; DSM-IV (33, 34, 36-39, 41-47), ICD-10 (35, 36, 50, 51) and ICPC-2 (40).

Johnsen et al., in a Norwegian national survey from 2020, found that amongst an average of 20 daily consultations, GPs addressed mental health disorders in 22 %, stress and life strains in 20 % and multimorbidity in 29 % of consultations (52). Rosendal et al. studied ICPC-2 diagnoses in Danish primary care by questionnaires to GPs. They found GPs to set a psychological diagnosis in 11 % of consultations (40). Lejtzén et al., in a large Swedish cohort study from primary care registry data, found a total prevalence of 2.4 %, only including mood-, anxiety-, stress- or adjustment ICD-10 diagnoses (51). Sundquist et al., in another Swedish primary care registry cohort study, found that major depression was present in 12 % and anxiety disorders in 10 % of patients (50).

1.2 General practice

"In general practice, we form relationships with patients often before we know what illnesses the patient will have. The commitment, therefore, is to a person whatever may befall them."

*Ian McWhinney (*53*)*

1.2.1 The generalist approach

General practice is the usual first contact between doctors and patients in our healthcare system. GPs office centres are situated in local communities, in direct and continuous contact with the population they serve. They tend to their patient's health needs, and GPs act as coordinators of patients' health care from the different specialized sections of our healthcare system (54).

General practice is responsible for consulting with patients' overall health needs, making it holistic and integrative (53, 55-57). As it pertains to general practice, 'holism' has been challenging to define, as it may exist in many different dimensions (55). As Joshua Freeman writes in his paper "Towards a definition of holism"; "For a cell biologist, holism might mean thinking about the whole liver" (55). Ian McWhinney wrote in his article, "Being a general practitioner, what it means", that; "As general practitioners, we have to be prepared to work at all levels of abstraction, according to need" (53). Further in his abstractions on the generalist approach, he goes on to state that;

> The clinical method of internal medicine does not include the examination of the emotions; the clinical method of psychiatry does not include the examination of the body. The essence of our clinical method in general practice is that the body, the emotions, and the patient’s experience of illness are attended to in every case (53).

Biomedical knowledge is integral in general practice as it is in specialized care. It provides evidence-based practice and diagnostic, prognostic, and therapeutic services for various biomedical conditions. Nevertheless, beyond the knowledge of disease is the knowledge of the patient as a human being (58).

The character of the problems encountered is specific to each patient, reflecting their psychological and social functioning and circumstance. The context in which these encounters take place is also specific. On the other hand, the symptoms presented are often undifferentiated and unspecific (59, 60). The GP's role is to offer a degree of clarity about the nature and cause of such problems, and to guide their management, even if the causes of a patient's symptoms are not immediately clear by either patients or their doctors in the beginning (16, 61, 62).

Continuity of the doctor-patient relationship is another vital aspect of general practice and is valued by patients (63). Continuity of care is associated with reduced specialist healthcare use, fewer acute hospital admissions and lower mortality (64-66). In addition, continuity of care in the form of a regular GP is associated with doubling the odds of receiving mental health care for patients with mental distress (67).

Paul Freeling described general practice as “organizing the chaos of the first presentation” (68). This statement goes to the heart of general practice, acknowledging that patients are often in distress and come to their doctor for help to alleviate their symptoms and resolve their situation (69). Therefore, general practice may be an ideal environment to make sense of these often complex interactions between physical and psychological health problems (61).

1.2.2 Norwegian general practice

Norway operates with a patient-list system where all inhabitants are listed to a GP of their choosing (70). This regular general practitioner (RGP) scheme was implemented in 2001. The Norwegian Health Economics Administration manages the scheme, but the municipalities are responsible for entering into agreements with individual GPs (71).

All inhabitants registered in the National Population Register as living in Norway have the right to a RGP. Every RGP in Norway has a list of patients with defined responsibilities in the follow-up and care of their patients. About 98 % of the population have their RGP, only 0.2 % of the population choose not to, and overall satisfaction is high (72-74). However, as of February 2022, The Norwegian Directorate of Health reported that 150 000 inhabitants stand without a RGP due to the ongoing GP crisis resulting in a lack of recruitment of new RGPs (75).

The system is funded by a capitation component based on the number of patients on the RGP’s list, a fee-for-service component (reimbursed by the state in a tariff system), and relatively modest co-payments by patients. All medical contacts require a diagnostic code to be valid for reimbursement by the state. The average list size in 2020 was 1068 patients, slowly declining from around 1200 patients in 2005 (76).

Morken et al., in a national observational study from 2018, found that the mean total working hours per week for Norwegian RGPs was 55.6 (77). Only 54.1 % of the regular hours were used on face-to-face patient work (77). Johnsen et al., in a Norwegian nationwide survey from 2018, found that RGPs carry out 20 consultations a day, addressing 43 different issues on a typical day in their practice (52).

1.2.3 Frequent attendance in general practice

It is a well-known phenomenon that a smaller portion of patients, here called frequent attenders (FA), have a relatively high frequency of consultations with healthcare services and therefore compose a significant part of a GPs workload (78, 79).

The definition of frequent attendance varies between studies (80-82). However, in a systematic review from 1999, Gill et al. lay out two general approaches: One is to identify a cut-off point in the distribution of patients, such as the top quartile or top 10 % stratified by age and sex. The other is based on a minimum number, such as a cut-off of at least eight consultations per year (79-81, 83).

Vedsted et al. performed a literature review and found that the top 10 % of patients accounted for 30-50 % of all contacts in Danish general practice, and up to 40 % of these patients were still FAs the following year (81). Jørgensen et al., in a Danish cohort study from 2016, found that FAs accounted for 40 % of all face-to-face consultations with a GP, with a mean of 12 visits per year (84).

Studies consistently confirm that FAs have higher rates of mental distress, mental health disorders, and social difficulties (78, 79, 81, 85-92). Being female and increasing age is also highly associated with frequent attendance (78, 81, 84, 93, 94), although in a systematic review from 2020 including only longitudinal studies, Hajek et al. found that younger age (as well as unemployment and need factors) were also associated with becoming a FA (95).

What drives FAs to help-seeking behaviour? Norbye et al. found that health anxiety was associated with increased utilization of primary-, somatic, and mental specialist health care in a dose-response fashion in a Norwegian cohort study from 2022 (96). Strömbom et al., in a Swedish study from 2019, also found that perceived ill health, particularly pain and distress, was important for utilising healthcare resources for FAs (97).

1.3 Symptoms

“*Symptoms are literally a fall from our usual state of functioning. Symptom-free, we can focus our full attention and energies on the world around us. Symptomatic, we focus inward, distracted from what we know can and should be done.*”

Kurt Kroenke (98)

1.3.1 Symptoms in general practice

Symptoms of all kinds are common in the community (99-101). Most of these symptoms will resolve spontaneously, but some symptoms become more persistent or recurrent (102). Only about one in four patients contact medical services for their symptoms (32, 103), the usual first contact being their GP (103).

A clear definition of ‘symptoms’ in general practice is an ongoing discussion (104). WONCA Dictionary of General/Family practice defines symptoms as “any subjective evidence of a health problem as perceived by the patient” (105).

Symptoms are often perceived as either ‘physical’ or ‘psychological’. Physical symptoms are often called ‘somatic’ by psychiatrists and psychologists in the context of mental health disorders (106). However, we often encounter symptoms without apparent medical explanation (103, 107). In general practice, these are often labelled as “medically unexplained symptoms” or “MUS” (108). It is an ongoing discussion trying to establish whether or to what degree patients with long-standing somatic symptoms have underlying mental health disorders (102, 109, 110). Correctly diagnosing patients with yet unclarified symptoms can be a challenge for GPs (109). Still, The WONCA Europe Research Agenda states it is a core competency in general practice (111).

1.3.2 Somatic symptoms and mental health disorders

Many studies have established and explored the associations between somatic symptoms and mental distress (112, 113) or diagnosable mental health disorders (43, 101, 106, 112-135) in general practice.

Several studies have found that increasing somatic symptoms increases the probability of also having a mental health disorder (127, 130-132). This points towards the sum of somatic symptoms, more so than the specific type of symptom, as the strongest predictor of mental distress or mental health disorders. However, this is not a straightforward issue (15, 136).

Depression is the most common mental health disorder studied in general practice, and pain is the somatic symptom most studied concerning depression. They are found to co-occur in 30-50 % of cases (137, 138). Somatic symptoms are common in depression and have been stressed as one of its core features (118, 139). Studies have tried to define the directionality of this association. Fishbain et al., in a literature review from 1997, concluded that depression is more likely to be a consequence of pain than preceding it. Still, the conclusion was based mainly on cross-sectional studies (140). Nakao et al. found that three somatic symptoms (low back pain, dizziness and abdominal pain) were significant risk factors for developing major depression the following year (116). Kroenke et al., in a 12-month longitudinal study from general practice, found that pain and depression have strong and similar reciprocal effects on one another (115). Yamamoto et al. found that depression was related to somatic symptoms, such as fatigue, sleep disturbances, loss of appetite and weight loss. Although interestingly, for patients without these three reported symptoms: general fatigue, sleep disturbance and appetite loss, none of the patients met the criteria for depression (130).

Dijkstra-Kersten et al. explored longitudinal associations of having multiple somatic symptoms and the recurrence of anxiety and depression disorders over four years.

They found that patients with multiple somatic symptoms had an increased probability of recurrence of anxiety and depression, regardless of initial depressive and anxiety symptoms (133). Van Boven et al., in a longitudinal study over ten years, found that somatic symptom episodes presented in general practice were predictive of anxiety and depression. Presenting two or more symptom episodes in general practice increases the risk of anxiety and depression five-fold (128). De Waal et al. studied individual somatic symptoms associated with mental distress in general practice. They found that patients with high mental distress reported all types of somatic symptoms more often than patients without mental distress (113). Finally, Bekhuis et al. explored the differential associations between depressive and anxiety disorders and somatic symptoms. They found that all clusters of somatic symptoms were associated with anxiety or depression, and depression and anxiety disorders were independently related to somatic symptoms. Major depressive disorder showed the strongest associations in their material (135).

1.3.3 Handling somatic symptoms in general practice

Many patients do not link their mental distress and their physical symptoms and present to their doctor, wanting an explanation (141). Several studies have found that patients with diagnosable mental health disorders, such as depression, may only present somatic symptoms when consulting a doctor, especially before they have developed a trusting relationship with a GP (114, 119, 121, 127, 129).

Non-specific symptoms may represent severe illness, which makes GPs inclined to investigate somatic symptoms first, and risk becoming preoccupied with investigations into possible underlying organic disease before considering mental health disorders (119, 129). In addition, these somatic symptoms may sometimes dominate the clinical picture to such an extent that the patients perceive their illness to be physical, affecting their wants and needs in a consultation. This may increase the risk of overuse of health services and possible harm (139, 142).

Heinz et al. found that nearly half of patients with depression only reported physical complaints to their GP, and they reported twice as many symptoms as patients without depression. In addition, patients with depression showed higher perceived stigma than those without depression (127). Simon et al. found that a somatic presentation of underlying mental distress was more common when patients lacked an ongoing relationship with a GP (129), pointing towards the importance of continuity of primary care (66).

These somatic symptom presentations may be a challenge for diagnosing mental health disorders in general practice (143). Still, many GPs perceive somatic symptoms as possible presentations of social or emotional distress (144, 145) and generally find common symptoms and complaints meaningful to deal with (146). In conclusion, GPs are well-placed to detect mental health disorders in patients presenting with physical complaints (147).

1.4 Diagnosis

"With a diagnosis, things do not necessarily get better, but they become clearer."

Annemarie Goldstein Jutel (148)

1.4.1 Diagnosing mental health disorders in general practice

Diagnosis is both a process and a label and is used to organize a clinical picture and guide medical care (149, 150). Ian McWhinney explored the diagnostic process in general practice in his paper "The importance of being different" (57). Here, he illustrates with a story by the author Umberto Eco. In this story, a monk describes:

> If you see something from a distance, and you do not know what it is, you will be content in defining it as an animal, even if you do not know whether it is a horse or an ass. When it gets closer, you will see it is a horse, even if you do not yet know its name. Only when you are at the proper distance will you see that it is Brucellus, the abbot’s horse, and that will be full knowledge, the learning of the singular (57).

McWhinney uses this story to illustrate the different levels of abstraction used in medical diagnosis. Medicine has gained knowledge and predictive power by distancing itself enough from individual patients to see the abstraction (the disease). This process is crucial, but as we move towards the person, we move towards the particulars, where every patient is different. The patient-centred method is characteristic of primary care (151-153). Andre et al., in their study of strategies used by GPs in clinical decision-making, found that GPs tend to focus on both the symptom and the person and shift between these strategies in their clinical decision-making according to need (154).

Patients in general practice present with various mental health problems that are often difficult to categorize or define as distinct mental health disorders. In the beginning, deciding whether something is a “natural reaction” or a pathological pattern that needs intervention is not necessarily easy to distinguish (155). A diagnosis might not be made in a single assessment but is often a process arrived at with time (156-158). Many patients have mild and passing symptoms of mental distress, perhaps related to specific life challenges. Chin et al. studied the 12-month naturalistic outcomes of depression in primary care. They found that 60 % had complete remission of their symptoms during the year, while 40 % of patients continued with a chronic or recurrent course of depression. The identification of depression by a GP did not affect the outcome after 12 months, but they found that identified cases were linked to faster recovery (159).

GPs in the primary care system need high-quality tools and knowledge that is valid and useful in recognizing patients suffering from severe psychiatric illness to be able to refer these patients for proper psychiatric treatment. Still, there are good arguments for being restrictive with labelling patients in primary care with a mental health disorder regarded as an illness (136).

The existing disease-oriented view in medicine today classifies symptoms and impairments as the subjective and objective presentations of underlying diseases and diseases as manifestations of pathology (160). However, when diagnosing mental health disorders, we are not diagnosing easily observable physical phenomena but mental processes (161). The various symptoms presented in general practice are still presented as distinct entities, and each diagnosis or disease is recommended to be managed according to agreed, best-evidence guidelines.

Specialists in psychiatry have mainly developed the diagnostic classification systems of mental health disorders today, consisting of only behavioural descriptions, with no biological fundament to define them. Such a diagnostic translation may fail to disclose what is going on in the patients' life, their social circumstances, trauma history, patient's function in day-to-day life, and how their illness behaviour is affected by their life histories in general practice. What is problematic is the process of translating patients' histories and often mixed presentation of symptoms into distinct diagnostic categories and labels. Sturmberg et al. point out that even if a diagnosis is essential, it has become a dissecting, splitting, and deductive approach. We need to also envelope the opposite, integrative view when diagnosing patients with mental distress in general practice (162).

Richard J Goldberg points out in an article from 1993 that mental illness, such as depression, may be different in general practice from how it presents in mental health settings. Nevertheless, studies in mental health populations typically set standards for recognition and treatment in primary care (163). This tendency is coherent with studies finding that GPs use different constructs when diagnosing mental health problems compared to psychiatric specialists (143, 164, 165). Few studies are exploring the differences in patient populations and with varying results. For example, Vuorilehto et al. found few differences between depressed patients in primary versus specialized care (166). In contrast, Suh and Gallo point toward apparent qualitative differences indicating that patients with depression present differently in specialist versus primary care (167).

The World Psychiatric Association (WPA), in collaboration with WONCA, conducted a global survey in 2019 where they asked all presidents of the different member associations of WPA about mental health core competencies in general practice. They found that the representatives of psychiatry specialist organizations asked found the core competencies in primary care important and valuable. However, they did not think GPs currently possess these competencies (168).

To what degree criteria for mental health disorders defined in specialist care is valuable and valid in primary care, or if differences in patient populations require a different structural basis to enhance current practice, is still unanswered (15, 165, 169). This statement does not mean that mental health disorders do not exist or that diagnostic thresholds are entirely arbitrary. However, it does indicate that diagnosing mental health disorders involves a certain level of subjectivity and gives room for flexibility (150, 161). Some argue that we need to establish new concepts to address the level of complexity in general practice, where all kinds of health problems presented are not always caused by distinct medical illnesses (15, 169, 170).

Joanna Reeve criticizes this disease orientation over interpretive thinking in evaluating patients and their mental health in general practice in her article “Interpretive medicine. Supporting generalism in a changing primary care world” (17). She argues that we need a more flexible framework for understanding and valuing knowledge in general practice. She stresses that general practice is about the interpretation of illness, not only about the identification of disease (17). This argument is coherent with others arguing that we need to shift focus and establish new concepts and methods that may be more suitable for primary care (152, 153, 160, 171).

1.4.2 How skilled are GPs in diagnosing mental health disorders?

Numerous studies have pointed towards unsatisfactory recognition of mental health disorders in general practice (156, 158, 164, 165, 172-197). Studies with origin in specialist care (158, 164, 172-176, 181, 182, 193-196), general practice (156, 165, 177-180, 184-186, 189, 190, 192) or a combination (183, 187, 191). Most of these studies explore to what extent GPs diagnose defined mental health disorders, such as depression or anxiety. Fewer studies have explored how GPs identify general mental distress in their patients (158, 185, 193, 198).

Results vary, but many studies conclude that GPs only recognize around half of the patients with diagnosable mental health disorders in primary care. Some show results of as low as 30 %, others as high as 70-80 % of patients being correctly identified with a disorder (179, 180, 184, 195). In a study from the Nordic countries, Munk-Jørgensen et al. found that GPs recognize between one-third and half of the patients with generalized anxiety in primary care (197). From a more global perspective, Fekadu et al., in a systematic review from 2022, found that numbers were even lower in low- to middle-income countries, all the way down to zero per cent in some studies (199).

The underlying reasons for this apparent lack of recognizing mental health disorders by GPs are complex and multifaceted. They include factors regarding the GPs, patients, the structure of primary care and general practice, and the structure in which mental health disorders are diagnosed, including different criteria for different diagnostic systems in use (200).

In a meta-analysis from 2010, Mitchell et al. found that GPs were better able to recognize distress than mild depression in their patients. Still, only one in three patients was correctly diagnosed (201). Thompson et al. found that GPs seemed to be better at recognizing depressive symptoms by taking a dimensional approach to the severity of symptoms than found in studies with a categorical approach to depression (202). Indeed, studies show that the severity of symptoms increases the probability of being recognized with a diagnosis (203). Recognition of mental health problems in primary care often depends on the severity of symptoms and the level of comorbidity amongst patients (179, 183).

Mental health disorders that remain unrecognized in general practice tend to be milder, more self-limiting, and associated with less disability (173, 174, 179, 180, 183). Studies show varying results on the effect of outcomes of increased recognition. Some studies find that correct diagnosis affects management and outcome (172, 173) and others that it does not (172, 174, 177, 186). In these studies, patients that go unrecognized show a similar rate of improvement over time as recognized cases.

GP recognition of mental distress varies with different criteria for recognition (175). The preciseness of GPs diagnoses compared to standardized research diagnoses has been explored, finding that they differ (164, 184, 195). This indicates that the misidentification of mental health disorders in general practice may partly be explained by the use of psychiatric models of diagnoses in a primary care setting (165). In a meta-analysis from 2009, Mitchell et al. found that GPs' misidentification of non-depressed patients was more common than missed cases of depression. However, the accuracy of diagnosis increased with prospective examination over 3-12 months rather than evaluating one-off assessments (204).

Indeed the level of continuity of care has been shown to increase recognition (185). The probability of diagnosing a mental health issue increases with the number of GP contacts and the duration of the doctor-patient relationship (156-158, 189, 194). This finding indicates that continuity in the doctor-patient relationship is essential, but studies also find varying results. For example, Sun et al. found that patients with a regular GP had around double the odds of receiving mental health care (67). In contrast, Ridd et al. did not find that continuity of care affected the recognition of mental distress in patients by GPs (185).

Depression is less likely to be recognized in patients with somatic symptoms than in patients with predominantly psychological symptoms (175, 178, 194) and patients who normalize their symptoms in consultation with a GP (193). This is particularly apparent during initial visits to a GP before a trusting relationship is established between the patient and the doctor (129).

Joling et al. explored GPs' health records and found that GPs were aware of mental health problems in most patients but that the use of diagnostic codes was weak, indicating that using diagnostic codes alone is not an accurate measure of diagnostic ability and may strongly underestimate the accuracy of the GPs diagnostic evaluations (205).

A criticism towards many studies indicating a significant level of non-recognition of mental health disorders by GPs is their often cross-sectional design. Taking a cross-sectional “snapshot” of the prevalence of unrecognized patients with diagnosable mental health disorders may overestimate this prevalence. Cross-sectional studies fail to reflect the longitudinal nature of primary care that allows patients to be diagnosed on subsequent visits or heal spontaneously without requiring further investigation and treatment (157, 159). Arriving at a diagnosis in general practice is not always done at the first visit. Studies using a single index visit may incorrectly classify cases as non-detected (156).

Tylee and Walters address the apparent under-recognition of mental health disorders in general practice in their 2007 article “Underrecognition of Anxiety and Mood Disorder in Primary Care: Why Does the Problem Exist and What Can Be Done?” They acknowledge methodological challenges, asking if the methods can capture the complexities of recognition in primary care, but still conclude that there is room for improvement (206).

1.4.3 GP perspectives

Studies find that GPs are often aware of mental distress in their patients, but they are cautious about diagnosing a mental health disorder (207-209). They often see the psychiatric classification systems as less valid in primary care. They have a more longitudinal approach to diagnosing mental health disorders, emphasising patients' context and situation (207, 210-212).

Chew-Graham et al. found that GPs conceptualize depression as a common and normal response to life events rather than an objective diagnostic category (213). Geraghty et al. found that GPs find it difficult to separate emotional distress from a depressive disorder and tend to focus on physical symptoms such as poor sleep, appetite change and insomnia as well as loss of function when considering a depressive disorder diagnosis (214).

Significant barriers to making a diagnosis amongst GPs have been explored, the most important being the potential stigma of a diagnosis as experienced by patients and patients having difficulties accepting a diagnosis. GPs also emphasize the lack of time and resources and lack of collaboration with specialized health care (212, 215-217).

GPs require sophisticated consulting skills to differentiate a wide range of symptoms from a complex narrative in a short period of time (119). Carney et al. found three main approaches that GPs used in a consultation: A biomedical exclusionary approach, addressing physical complaints first; a mental approach, where psychosocial aspects were in focus; or a synergistic approach, where physical and mental health problems were addressed simultaneously. GPs would move freely across all approaches depending on patient clues (218).

Andre et al. explored how GPs focus on either 'symptoms' or 'the 'person' in consultations and found that they shift between both approaches according to need. Immediate, inductive, as well as gradual, analytical decision-making were both common (154). Davidsen et al. showed that GPs find it important to help patients understand the meaning of their symptoms in their complex life situations. The GPs do this in different narrative styles mirroring their patients' mental states (62). GPs value continuity of care, as it aids in open and trusting communication (216, 217). Barnes et al. found that GPs find it challenging when patients do not accept their symptoms as representing mental distress. They would sometimes wait to address these issues and set patients up for repeat appointments to address anxiety or mood separately from patients presenting complaints (216).

1.4.4 Patient perspectives

Patients value a good relationship with their GP, which is especially important when disclosing mental health problems (216, 219, 220). Patients value attentive doctors who show genuine interest and understanding, and the perceived support by their GP is valued as a core part of treatment and support (219-222). Patients value feeling listened to, even going beyond, and expressing how their doctors' listening makes them feel more understood and accepted (223, 224). Patients value a connection with their doctor and explanations for their symptoms over treatments such as medication (219, 222, 225, 226). It is experienced as negative when their doctor is not listening and paying attention (223).

Parker et al. found that patients experience the relationship with their GP as intrinsically healing but still find it challenging to open up, fearing stigma, and often feel the need to “start off” addressing a physical concern (219). Patients are often puzzled by their symptoms, not always recognizing their emotional problems, and value GPs as collaborators when trying to unfold possible underlying mental aspects of their symptoms (215, 219, 223).

Patients value the continuity of care in general practice in the form of a trusting relationship and appreciate when GPs prioritize personal continuity by booking follow-up appointments for them (219, 223, 227). Conversely, a lack of continuity and a trusting relationship is presented as a barrier to disclosing mental health problems to their GP (215, 227, 228).

Patients with emotional concerns often express difficulty in discussing their problems. They tend to wait until the end of the consultation before sharing emotional concerns, which may hinder time to focus on these issues (190). In addition, they tend to feel that emotional concerns are not a legitimate reason for seeing a doctor (220, 229). Patients are also aware of time constraints during GP consultations, which may lead to non-disclosure (220, 230, 231). Dew et al. found that although patients expressed high trust in their doctors, non-disclosure of mental distress was common. The main barrier expressed were fear of consequences and losing their sense of control if they disclosed mental health problems to their GP (227).

Patients experience the risk of stigma as an important barrier to disclosing mental health problems to their GP (129, 215, 219, 227, 232). A systematic review from 2018 found that stigmatizing attitudes towards people with mental health disorders are still common among GPs (233).

2 Aims of this thesis

This thesis aims to explore mental health problems in general practice by studying the prevalence and distribution of patients with psychological diagnoses, their related frequency of consultations, associations between psychological and somatic symptom diagnoses, and whether GPs diagnoses correspond with patient-reported levels of mental distress.

Paper I: We aimed to study the prevalence and distribution of GP-assessed psychological diagnoses and the related frequency of consultations. We wanted to assess if patients with psychological diagnoses consulted more frequently than patients without such diagnoses and how these matters varied with patients' age and sex and between individual GPs.

Paper II: We aimed to investigate the prevalence of somatic symptom diagnoses in patients with or without depression-, anxiety- and stress-related diagnoses, whether the number of somatic symptom diagnoses increased the probability of having a psychological diagnosis, and how individual somatic symptom diagnoses correlated with having received anxiety, depression, or stress-related diagnosis in general practice.

Paper III: We aimed to explore whether patient-reported mental distress corresponds with having received a psychological diagnosis from a GP and whether patients' age, sex, number of consultations and number of somatic symptom diagnoses influenced the probability of having received a psychological diagnosis.

3 Material and methods

3.1 Shared Care and Usual Health Care for Mental and Comorbid Health Problems

This thesis emerged from a larger research project titled; “Shared Care and Usual Health Care for Mental and Comorbid Health Problems” (234). This is a cluster-randomized controlled intervention study that took place in six GP office centres in three boroughs in Oslo, Norway, from 2014-2018.

This main study aimed to explore whether collaborative primary and mental health care could improve accessibility and affect health care for patients with mental health problems. For each participating borough, one GP office centre was randomized to pilot a collaborative care model between GPs and mental health care services, while another GP office centre continued with usual health care. Data from electronic medical records from all six GP office centres were extracted for 12 months before implementation, and a questionnaire study with patients was performed before the intervention to provide baseline information. These baseline data are the basis of this thesis.

3.2 Design

We performed cross-sectional analyses of electronic medical records from a cohort of patients from unselected general practice. We used descriptive comparative designs to study associations and differences between groups. For Paper III, we did cross-sectional analyses from both electronic medical records and patient questionnaires.

3.3 Setting

This study took place in six GP office centres with 35 participating GPs in three boroughs (Alna, Stovner, and Grorud) in Groruddalen, Oslo, Norway. Groruddalen is the largest suburb of Oslo, with approximately 140 000 inhabitants, and lies northeast of the city centre. Approximately 50 % of inhabitants have an immigrant background (first to third generation). The area has lower economic and social welfare scores compared to the rest of Oslo and Norway as a whole. During the last 15 years, significant national and municipal resources have been provided to this part of our community to correct this social and economic imbalance.

3.4 Data collection

3.4.1 Recruitment of participants

The recruitment of GP office centres followed the principles of convenience sampling. The order of invitation was by equality in the size of the offices between the boroughs (offices with 4–6 GPs were prioritized before offices with one, two, or more than six GPs). The centres were contacted by telephone. Once a meeting was set up, other research group members (senior GP and psychiatrist) also attended in meeting with the GPs to give information about the project. The GPs would then decide on participation before signing a detailed contract. Nine GP office centres were contacted before six agreed to participate.

3.4.2 Clinical cohort

We extracted data from all patients aged 16-65 at inclusion, defined by the last date from when the questionnaire study for each participating GP office centre was performed. Data was extracted 12 consecutive months retrospectively from this date in 2015. Later in the project, we extracted nine months of electronic medical records from each centre's inclusion date, but now only for the patients included in the questionnaire study. This period could not be extended to 12 months, as it might have been affected by the intervention in the main study. This gave a 21-month cohort of patients analysed for Paper III.

The age and sex of patients were extracted by national identification number. In addition, all contacts with the GP office centres were included, as were the type of contact, ICPC-2 diagnostic codes per contact, the GP responsible for each contact, and reimbursement codes used by the GPs. A computer program developed by the firm Mediata AS was used to extract data from the different software programs used in the GP office centres.

The electronic medical records from 17,973 patients and a total of 111 870 contacts were extracted. Of these, 16,845 patients had one or more direct contacts with their GP, either in the form of office- or home visits. These accounted for 68,814 contacts during the 12 months, forming the clinical cohort used in this thesis. The remaining excluded contacts were either phone calls (with the office centres, not necessarily with a GP), letters, prescriptions, or interdisciplinary meetings.

The data were registered and kept at an approved and secure research server at Akershus University Hospital, then eventually moved to a secure research server service at the University of Oslo.

3.4.3 Questionnaire study

All patients entering the six GP office centres for two weeks in 2015 were invited to fill in a questionnaire. The questionnaire consisted of CORE-10, a comprised version of the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) (235). All participants were given written information about the study, available in Norwegian and English. They gave written consent before participation. We were present during the recruitment period to administer the questionnaires to patients and assist with any questions or queries.

Patient anonymity was an important factor as we conducted our questionnaire study. We were given the identity of patients in their consent forms, which were coded to correspond with their questionnaire. These two forms were collected separately at the GP office centres to keep the answers separated from their identity. We did not register patients who did not agree to participate in our study, which gave us no information on the response rate or representativity of the sample in our analyses for paper III.

We collected 845 questionnaires in total. Of these, 215 questionnaires were excluded. This was due to the consent form not being filled out correctly or the national identification number being missing or incomplete. As we asked all patients in the waiting rooms, we also had to exclude the respondents outside of the age range (16-65 at inclusion). Another 77 were excluded because participants were not part of the cohort of registered patients at the offices. This left 553 questionnaires included in this study. The number of participants declining to participate was not recorded.

3.5 ICPC-2

The International Classification of Primary Care (ICPC) is the official classification system developed by the World Organization of Family Doctors (WONCA) and the diagnostic system used in Norwegian general practice (6). ICPC-2 indicates that it is the second version of the system.

The ICPC was designed specifically for use in primary care (236). ICPC is based on empirical data and contains codes to reflect the content and level of detail deemed appropriate for a primary care setting (6). The diagnostic classification system is accepted by WHO as a member of the Family of International Classifications and is translated into over 20 languages (236). ICPC-2 has, in its revised form, also been mapped to the International Classification of Disease (ICD-10), a classification system widely used in other areas of medicine today (6).

ICPC-2 is divided into 17 chapters that cover medicine at large. It is a biaxial classification system consisting of one letter and two digits. The letter forms an axis indicating an organ or body system, while the digits form an axis for symptoms, complaints, and process elements. The numbers 00–29 indicate symptom diagnoses, while 70–99 indicate disease diagnoses, although with some overlap.

ICPC includes symptom diagnoses. These diagnoses are helpful in general practice where symptoms may present early in the course of illness, be more undifferentiated and perhaps passing and not indicative of more serious underlying disease (59). It has been recommended that symptoms be accepted as equivalent to disorder diagnoses when they are a more accurate description of the level of clinical certainty found in general practice (237, 238).

ICPC is constructed to code all reasons for encounters and procedures and all end-of-visit codes (6, 59). In Norway, ICPC-2 is used to document reasons for encounters (239). All contacts with GPs are registered with one or more ICPC-2 diagnostic codes in the electronic medical records. The code must be coherent with the content of written, electronic medical records for that same contact (239) and is sent to the government to obtain reimbursement in a government-aided tariff system. In addition, each documented contact is registered in an extensive registry of information owned by the Norwegian Directorate of Health (240). Data from this database is used by institutions such as the Norwegian Institute of Public Health to monitor the population's health and by Statistics Norway to provide statistics on the Norwegian General Practitioner Services (241).

3.5.1 Psychological diagnoses

The psychological diagnosis chapter (P) in ICPC-2 aims to be a comprehensive collection of mental health problems presented in general practice, ranging from symptom diagnoses (depressed feeling, feeling nervous) and disorder diagnoses (depressive disorder, anxiety disorder). This allows the GP to be more precise about the specificity of the course of illness as they present in general practice, even if these can often overlap (242).

All the different psychological diagnoses were included in Paper I. Paper II focused on the most common mental health problems from Paper I. These included anxiety (feeling anxious/nervous, anxiety disorder), depression (feeling depressed, depressive disorder) and stress-related diagnoses (acute stress, PTSD). These ICPC-2 diagnoses and their corresponding International Classification of Disease, 10th edition (ICD-10) diagnoses are described in more detail in Online Table 1 in Paper II (see appendix).

3.5.2 Somatic symptoms diagnoses

Somatic symptom diagnoses refer to all the symptom diagnoses (00- 29) from each ICPC-2 organ chapter. These were the diagnoses included in the ‘somatic symptom diagnosis’ variable in Paper III. Paper II also included diagnoses representing functional syndromes or symptom clusters commonly associated with mental health disorders in the literature (30). These diagnoses comprised: stomach function disorder, irritable bowel syndrome, vertiginous syndrome, elevated blood pressure (not including essential hypertension), neck syndrome, back syndrome without radiating pain, back syndrome with radiating pain, shoulder syndrome, tension headache and hyperventilation syndrome. These ICPC-2 diagnoses and their corresponding ICD-10 diagnoses are described in more detail in Online Table 1 in Paper II (see appendix).

3.6 Clinical Outcomes in Routine Evaluation –CORE

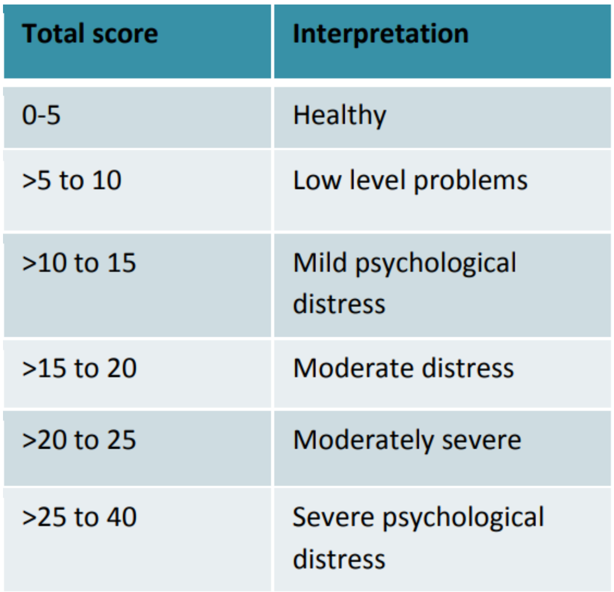
The Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM) is an instrument developed for use in therapies across different settings (235). The original motivation was to find a single measure – a ‘core’ for monitoring work with mental health. There are many measures in routine use with little comparability across services (243). This measure has been tested with high internal reliability and test-retest stability within clinical and non-clinical samples, is translated into several languages and is widely used (244).

Over time a shortened version of the CORE-OM was developed, suitable as a screening tool for general mental distress (245). The CORE-10 comprise the following: depression (two items), anxiety (two items), functioning (three items), trauma (one item), physical (one item) and risk (one item) (246). The questionnaire has an approved Norwegian version. It has been explored and shown to have psychometric properties at the same level as the English original and is recommended for general clinical use (247).

3.6.1 CORE-10 scoring system

Each item within CORE-10 is scored on a 5-point scale ranging from 0 (not at all) to 4 (most or all the time). The clinical score is calculated by adding the response values of all ten items. Where there is missing data, the clinical score is derived by dividing the total score by the number of completed items and multiplying by 10 (246). A score of 10 or below denotes a score within the non-clinical range, and 11 or above is within the clinical range of mental distress (245, 246).

Table 1 Scoring system in CORE-10 from Connell, J. & Barkham, M. (2007). CORE-10 User Manual, Version 1.1. CORE System Trust & CORE Information Management Systems Ltd**.**



Total score	Interpretation
0-5	Healthy
>5 to 10	Low level problems
>10 to 15	Mild psychological distress
>15 to 20	Moderate distress
>20 to 25	Moderately severe
>25 to 40	Severe psychological distress

3.6.2 CORE-10 updated version

As of February 2022, the original CORE-10 scoring guidelines have been updated to CORE-10 v1.1. Given the small number of items, it is not advised to compute a score if more than one item is omitted, as an omission of any item from a short but broad coverage measure can affect the relationship of a prorated score based on all the items. This clarification was done after Paper III was submitted for publication (Dec 17, 2021). We did not exclude questionnaires with less than nine items omitted in our Paper III.

3.7 Statistical analysis

3.7.1 Paper I

Descriptive statistics in frequencies (n) and percentages (%) were used to explore the distribution of psychological diagnoses. The number of consultations is described by means and standard deviations (mean ± SD). Differences in the mean number of consultations between participants with and without psychological diagnoses were analyzed using the independent t-test. Binary responses relating to whether a patient was given a psychological diagnosis or not by their GP were analyzed using a binary logistic regression model. We used the multilevel binary logistic regression to account for data clustering at the GP level. We obtained estimates of odds ratios (ORs) and their 95% confidence intervals from the model adjusted for patients' age and sex. Lastly, we estimated the intracluster correlation (ICC) from the adjusted model. Here, the ICC described the variation in giving a psychological diagnosis attributable to differences between the GPs. All analyses were performed using Stata SE 15 (Stata Corp, College Station, TX) and IBM SPSS Statistics 25 (Armonk, NY) and the significance level was set at p=0.05.

3.7.2 Paper II

Numbers were presented as frequencies, percentages, or means and standard deviations (SD). Generalized linear mixed models adjusting for possible cluster effects for each GP office centre in the data were estimated to perform the following analyses. First, the number of somatic symptom diagnoses (S-diagnoses) between the patients with and without any psychological diagnosis (P-diagnosis) was compared. Differences between patients with and without individual P-diagnoses were also assessed. This analysis was performed for all patients and stratified by sex and age groups (16–30, 31–50 and 51–65 years). The differences in S-diagnoses from different organ chapters and the individual most prevalent diagnoses (present among at least 1 % of patients with any of the included P-diagnoses), S-diagnoses between those with and without (any and individual) P-diagnoses were assessed. Finally, the association between the number of S-diagnoses and the probability of P-diagnosis was tested, and the results were illustrated graphically as probabilities with corresponding 95% confidence intervals (CI). Statistical analyses were performed by SPSS v26 and SAS v9.4. All tests were two-sided. Benjamini–Hochberg procedure was applied to control the false discovery rate due to multiple testing. The P-values indicating significant results after this adjustment were enhanced with bold-face.

3.7.3 Paper III

Descriptive statistics in frequencies (n) and percentages (%) were used to describe categorical variables, whereas numerical data were described by means and standard deviations. Mean differences between groups were analyzed using the independent t-test, whereas associations between categorical variables were analyzed using a Chi-square test. We performed binary logistic regression looking at factors associated with a psychological diagnosis. All analyses were performed using STATA SE 16 (Stata Corp, College Station, TX) and IBM SPSS Statistics 25 (Armonk, NY), and the significance level was set at p=0.05.

3.8 Ethics and approvals

The main research project was approved by the Regional Committee for Medical and Health Research Ethics (ref: 2014/435) and the National Committee for Medical and Health Research Ethics (ref: 2014/160). It was also approved by the Privacy Ombudsman at Akershus University Hospital (ref: 13/138).

3.8.1 Questionnaire study

The questionnaire study was approved by the Regional Committee for Medical and Health Research Ethics Region Southeast (ref: 2014/435) and the National Committee for Medical and Health Research Ethics (ref: 2014/160) as part of the main research project. Written and oral information about the study was provided with the questionnaire, and participants signed a written informed consent before participation. The patients’ consent included linking their information to data from the electronic medical records. This was done by the principal investigator using the national identification number used in Norway. Withdrawal of consent was possible for participants also during and after participation.

3.8.2 Rejection and appeal

The main project was initially presented to the Regional Committee for Medical and Health Research Ethics Region Southeast (REK) (ref: 2014/435). For the main research project, it was planned to obtain information from GP electronic medical records without the participants’ informed consent (234). This accounted for nearly 19 000 patients, and individual informed consent would be difficult to achieve for practical and financial reasons.

REK may grant access to the use of health information collected in the health services for use in research outside of the duty of confidentiality, cf. the Health Research Act §35 in the Norwegian judicial system. This can only be granted if such research is of significant interest to society, the interests of the participants’ welfare and integrity are taken care of, and REK can set the conditions for the use of the information. The committee decided that collecting data without consent was not in accordance with their remit and asked for informed consent from all participants.

The decision was appealed, and after the decision was upheld in REK, it was sent to the National Committee for Medical and Health Research Ethics (NEM), where this was approved (ref: 2014/160).

The principal investigator argued in the appeal that the secure retrieval of structured data from electronic medical records from GPs is in line with research conducted from national health registers that retrieve data from hospitals and other health services, where dispensation from the duty of confidentiality is often granted. Therefore, there should not be differential treatment as this would weaken the possibility of research-based knowledge to improve healthcare for a large group of people in primary care with disorders who already face stigma in society. It was also argued that the research would contribute to new knowledge that would be important to provide the population with a healthcare service more in line with the population's needs. Finally, it was argued that new knowledge would be of significant interest to the population and society and in concordance with the Norwegian Coordination Reform (248).

3.8.3 Disclosure

The author and supervisors report no conflict of interest regarding the study and the content and conclusions of this thesis.

3.9 Funding

Mina Piiksi Dahli has received financial support from the Norwegian Research Fund for General Practice (AMFF).

4 Synopsis of the articles

4.1 Paper I

Prevalence and distribution of psychological diagnoses and related frequency of consultations in Norwegian urban general practice

Mina Piiksi Dahli, Mette Brekke, Torleif Ruud & Ole Rikard Haavet

Scandinavian Journal of Primary Health Care (2020)

Aim: To investigate the scope of GP's work with mental disorders by studying the prevalence and distribution of GP-assessed psychological diagnoses and the related frequency of consultations.

Design: A cross-sectional study with data from 16 845 patients in 35 urban GP practices during 12 consecutive months in 2014-2015.

Results: Our material comprised 57 % females and 43 % males, with an average age of 40.1 years. Females accounted for 62.5 % of consultations.

18.8 % of all patients received one or more different psychological (P) diagnoses during the 12 months. Of these, symptom diagnoses alone were given to 48.4 %, disorder diagnoses alone were given to 37.0 % and both symptom and disease diagnoses to 14.5 % of these patients. There were 588 patients with two psychological diagnoses, 162 with three, 27 patients with four, four patients with five, and one with six different psychological diagnoses during the 12 months.

Depression was the most common P-diagnosis in the material, with depression symptom and disorder diagnoses together accounting for 27.9 %. Acute stress reaction was the second largest, with 14.9 % of P-diagnoses. Anxiety symptom and disorder diagnoses accounted for 13.5 %, and sleep disturbance 10.8 % of the total P-diagnoses.

The mean number of consultations was 4.1. We found a significant difference in the mean number of consultations, as patients with a P-diagnosis had 6.4 versus 3.5 for patients without any P-diagnosis during the 12 months ($p<0.001$).

Out of the 68 814 total consultations during the 12 months, 13.9 % ended in a P-diagnosis. Of these, females comprised 62.1 % and males 37.9 % of consultations. The most frequent attenders had an increased probability of having a P-diagnosis. Patients with eight consultations or more, comprising 14.2 % of patients, had a 41.2 % probability of having a P-diagnosis versus 15 % for patients with less than eight consultations during the 12 months ($p<0.01$). The top ten per cent of attenders accounted for 34.7 % of consultations compared to the bottom 90 % of attenders with 65.3 % of consultations. The probability of having a P-diagnosis among the top ten per cent of attenders was 43.3 % compared to 15.7 % for the bottom 90 % ($p<0.01$).

The odds of receiving a psychological diagnosis increased with age, and males were 17 % less likely to receive a psychological diagnosis than the females in the material. The patients visited with their regular GP (RGP) in 70.2 % of consultations, and the remaining 31.5 % with other doctors at the GP office. Including only consultations with their RGP, we found that 7.4 % of the variability in P-diagnoses could be attributed to differences between the RGPs when adjusting for patients' age and sex.

Conclusion: Psychological diagnoses commonly occurred in general practice, and patients with psychological diagnoses had a significantly higher number of consultations with a GP regardless of age, sex, and reason for contact.

4.2 Paper II

Somatic symptoms and associations with common psychological diagnoses. A retrospective cohort study from Norwegian general practice

Mina Piiksi Dahli**,** Jūratė Šaltytė-Benth, Ole Rikard Haavet, Torleif Ruud, Mette Brekke. Family Practice (2021)

Aim: To explore associations between depression, anxiety, stress-related diagnoses and somatic symptom diagnoses in general practice.

Design: Cross-sectional analysis with data from a cohort of 15 750 patients in 35 urban GP practices during 12 consecutive months in 2014-2015.

Results: Only patients diagnosed with depression symptoms or disorder, anxiety symptoms or disorder, stress symptoms or PTSD were analyzed. They were compared to patients with no P-diagnosis received during the 12 months. Patients with other P-diagnoses were not included in this study. Of the 15750 participants included in this study, 57.7 were females.

The somatic symptom diagnosis (SSD) distribution ranged from one diagnosis in 30.1 % of patients to 36 different SSDs in one patient during the 12 months. Patients with a P-diagnosis had a significantly higher number of SSDs with a mean (SD) of 2.9±3.6, compared to 1.9±2.5 SSDs for patients without any P-diagnoses during the 12 months ($p<0.001$). We found a significant increase in the mean number of SSDs for the included P-diagnoses viewed independently for both sexes and most age groups. In addition, the probability of a P-diagnosis increased significantly ($p<0.001$) with an increasing number of SSDs during the 12 months.

We found a significant increase in somatic symptom diagnoses from ICPC-2 chapters: General and unspecified, digestive, cardiovascular, musculoskeletal, neurological, urological, female genital disorders and social problems. There were small variations in associated symptom patterns for each included psychological diagnosis.

The symptom diagnoses most strongly associated with the total P-diagnosis group were general weakness/tiredness, dizziness, headache, palpitations, shortness of breath, stomach pain, musculoskeletal pain, dizziness, constipation, irregular menstruation, and lastly, a diagnosis code titled “General disease not otherwise specified”.

Conclusion: Patients with anxiety-, depression- and stress-related diagnoses had more somatic symptoms than patients without psychological diagnoses. The probability of having a psychological diagnosis increased with increasing somatic symptom diagnoses.

4.3 Paper III

GPs’ identification of patients with mental distress. A coupled questionnaire and cohort study from Norwegian urban general practice

Mina Piiksi Dahli, Ole Rikard Haavet, Torleif Ruud, Mette Brekke.

BMC Primary care (2022)

Aim: To explore how patients’ self-reported levels of mental distress correspond with psychological diagnoses made by their GPs and associations with sex, age, number of consultations and somatic symptom diagnoses.

Design: A questionnaire study coupled with 21-month cohort data from 553 patients aged 16-65 years in six GP offices in Oslo, Norway, in 2014-2016.

Results: This study included 553 patients, 69.4 % females and 30.6 % males, with a mean age of 43.1 years. The participants had a mean (SD) of 11.6 ± 7.6 consultations during the 21 months and a mean (SD) of 1.7 ± 1.7 number of different somatic symptom diagnoses. The total group had a mean CORE-10 score (SD) of 14.8 ± 5.6, bordering between mild and moderate levels of distress according to the CORE-10 clinical score categories. A total of 35.4 % of participants had received a psychological (P) diagnosis during the 21 months.

We found that 74.3 % of patients with high levels of self-reported mental distress versus only 13.3 % of patients with low levels of mental distress had received a P-diagnosis ($p<0.01$). In addition, we found a significant difference in the number of consultations ($p<0.01$), with a mean of 15.9 consultations for patients with high levels of distress versus a 9.1 mean number of consultations for patients with low scores for mental distress regardless of having a P-diagnosis. There was also an increase in somatic symptom diagnoses ($p=0.04$) and a higher number of females ($p=0.04$) in the high levels of distress group.

Comparing patients with or without a P-diagnosis in the material, we found that level of mental distress, mean number of consultations and being female were positively associated with having received a diagnosis. We found that level of mental distress ($p<0.01$) and number of consultations ($p<0.01$) were still highly significant factors in predicting whether patients had received a P-diagnosis after adjusting for sex, age, number of consultations, number of somatic symptom diagnoses and levels of mental distress respectively. We found that each unit increase in CORE-10 score and each additional consultation increased the likelihood of having a psychological diagnosis by 17 % (OR 1.17) and 7 % (OR 1.07), respectively.

Conclusion: There was a clear association between patients’ level of mental distress and having received a P-diagnosis in the material. The probability of receiving a P-diagnosis increased with increasing levels of mental distress and more consultations with a GP.

5 Discussion

5.1 Summary of findings

In Paper I, we found that almost 20 % of patients received one or more psychological (P) diagnoses during the 12 months. Around half were given symptom diagnoses only, around one-third were diagnosed with a disorder, and about 15 % were diagnosed with both. Depression was the most common diagnosis, followed by acute stress reaction, anxiety, and sleep disturbance.

Around 14 % of all consultations ended with a P-diagnosis, and patients with a P-diagnosis had a significantly higher number of consultations regardless of the reason for contact. This was true for both sexes and all different age groups. Amongst the most frequent attenders, we found a significant increase in the probability of having received a P-diagnosis during the 12 months.

In Paper II, we found that patients with depression, anxiety or stress-related diagnoses had received a significantly higher number of somatic symptom diagnoses for all the P-diagnoses studied separately for both sexes and most age groups. Each increase in the number of somatic symptom diagnoses received increased the probability of having received a P-diagnosis in the material. The symptoms most associated with having a P-diagnoses included general tiredness, dizziness, headache, stomach pain, musculoskeletal pain, autonomic symptoms, and irregular menstruation in females.

In Paper III, we found a clear association between the probability of a P-diagnosis and the level of patient-reported mental distress. Even so, only about 70 % of patients with the highest score of mental distress had received a P-diagnosis. We also found that patients with high levels of mental distress had more frequent consultations with a GP regardless of having received a P-diagnosis. Age and sex were not significant factors in the probability of receiving a P-diagnosis when adjusting for mental distress, age, number of somatic symptoms and number of consultations.

5.2 Discussion of results

5.2.1 Paper I

This is, to our knowledge, the first comprehensive study of psychological diagnoses in a complete cohort of patients through 12 months in Norwegian general practice. We found robust trends in our results, with statistically significant variations between groups.

We found that about 19 % of patients received a P-diagnosis. There are few comparable studies on the prevalence of psychological diagnoses from general practice. Most other studies incorporate diagnostic screening of a limited number of patients to estimate the level of mental health disorders in different GP populations. They also use different diagnostic classification systems, and although ICPC-2 is translatable to ICD-10 diagnoses, it makes the results more difficult to compare (200).

We did find an Irish study from 2016 using electronic medical records to determine the prevalence of mental health disorders in general practice. Gleeson et al. found an overall prevalence of 20 % (48). However, their study was small, and most disorders were identified only in the free text, as diagnostic coding alone would have failed to identify 92 % of patients with a mental health disorder.

We do not have nationally representative prevalence surveys on mental health disorders in the population to compare with (249). A Norwegian report from 2018 estimates that around 16-22 % of the adult population will suffer from a mental health disorder during 12 months, which overlaps with our results (28). This report also states that about 10 % of adult men and 15 % of adult women are in contact with primary healthcare services for mental health problems each year (28). Steel et al. found in a global prevalence study that 18 % of patients would suffer from a mental health disorder during a year, a result similar to ours (18).

Depression, anxiety, stress and sleeping disorders were the most frequently occurring diagnoses in our material, which is congruent with global prevalence studies on mental health disorders (18, 250). However, we found lower drug-related diagnoses than in other studies (19, 28). Suppose we summarise all the drug-related diagnoses from our material (chronic alcohol abuse, acute alcohol abuse, medication abuse and drug abuse). In that case, they only constitute 3.7 % of all patients in the material, 5.7 % if we include tobacco abuse. This could represent considerable underdiagnosis, perhaps also reflecting the patient population studied.

Most psychological diagnoses in the material were captured using just a few diagnostic categories. This corresponds well with Rosendal et al., who found that two problems (depression and acute stress reaction) accounted for 51% of all psychological classifications made from Danish general practice (40).

About 14 % of consultations ended in a P-diagnosis in our material, slightly higher than Rosendal et al., who found a P-diagnosis in 11 % of consultations in Danish primary care. Although in their study, they also included diagnoses only stated in free text and translated them into ICPC-2 codes (40).

The mean number of consultations for all patients was 4.1. This is higher than the Norwegian population, with an average of 3.0 yearly consultations in 2021 (251). We found that patients with a P-diagnosis had a significantly higher number of consultations, with a mean of 6.4 consultations versus 3.5 for patients without a P-diagnosis. This corresponds well with other literature showing that patients with mental health issues see their doctor more frequently than patients without these issues (39, 91, 252).

There are different definitions of frequent attenders in general practice. However, we estimated that the top ten per cent of attenders, as well as patients with eight or more consultations during a year, both had a significant increase in the probability of having a P-diagnosis compared to the rest of the patients. This is also coherent with other literature from primary care (79, 92).

We did not explore the comorbidity of different mental health disorders further, although other studies point toward the frequent co-occurrence of different mental health disorders (253). There were 26 % of patients with P-diagnoses that had received more than one different diagnostic code during the year. We could have explored the age, sex, and frequency of contact differences for the group with several versus one diagnostic code during the year.

5.2.2 Paper II

We found that patients with anxiety, depression and stress-related diagnoses had a significantly higher number of somatic symptom diagnoses compared to patients without any P-diagnoses during the 12 months, and this included both sexes and most age groups. This corresponds with several other studies from general practice (113, 126, 130, 135) and the general population (254, 255). We did not adjust for diagnoses of medical conditions that would explain different symptoms in each patient. We did not have information on the included patients' sociodemographic or lifestyle factors. The data consists of all patients in contact with the GP for 12 months. We expect a heterogeneous group of patients with various health conditions as they present in unselected general practice.

Patients with a symptom diagnosis (depressive symptoms, anxiety symptoms or acute stress reaction) had a significant increase in somatic symptom diagnoses compared to patients with diagnostic codes from the disorder section of ICPC-2 (depressive disorder, anxiety disorder, PTSD). This has been little explored in other studies from general practice and may indicate that these different diagnostic categories overlap.

The probability of depression, anxiety or stress-related diagnosis increased with an increasing number of somatic symptom diagnoses received during the 12 months. This has been explored in other studies, indicating that the number of somatic symptoms can be predictive of having a mental health disorder (131, 132). However, this is not a straightforward issue (15).

Looking at our results, patients with P-diagnoses had a mean of nearly three other somatic symptom diagnoses versus about two diagnoses for patients without any P-diagnoses. The results showed large standard deviations, indicating a high level of variability in the groups. Our results still showed a highly significant difference as we had a large cohort of over 15 000 patients included in our study. Still, according to our results, we will have difficulties finding patients with undisclosed mental health problems based on the number of symptom diagnoses alone until that number becomes relatively high. The number of symptoms, of course, must be seen in context with each patient’s other health conditions.

Bekhuis et al. explored differential associations of specific depressive and anxiety disorders with somatic symptoms in 2014. Their study included patients from both community, primary, and specialized care in Holland. They found that depressive and anxiety disorders were all independently linked to all the different clusters of somatic symptoms studied (musculoskeletal, cardiopulmonary, gastrointestinal, and general symptoms), and the associations were similar across the individual mental health diagnoses studied. This result corresponds to the findings in our study. Furthermore, after adjusting for chronic somatic diseases, sociodemographic and lifestyle factors did not substantially affect the results in their material (135).

We found significant associations with symptoms from nearly all the chapters in ICPC-2; General and unspecified, digestive, cardiovascular, musculoskeletal, neurological, urological, female genital and social problems (Supplementary Appendix for Paper II). It is important to note that we did find a significant difference on the chapter level for social problem diagnoses. However, they were not included in analyses of the individual symptom diagnoses in our material, as they occurred in less than 1 % of patients. Social problems are an essential aspect of mental health, as stated in a commentary article by Kato in 2022 (256). There may be considerable under-use of the social diagnostic codes in ICPC-2, but we do not have available data to verify this assumption. Rosendal et al. also found that social matters were rarely considered or classified (0.5 % of patients) in their study of ICPC-2 diagnostic codes in Danish primary care (40).

The symptom diagnoses associated with having anxiety, depression, or stress-related diagnoses were tiredness, dizziness, headache, musculoskeletal pain, abdominal pain, shortness of breath, palpitation, urine incontinence, constipation, and irregular menstruation. The diagnostic code “general disease not otherwise specified” was also included. We do not have more concrete information about when GPs chose to use this diagnostic code other than to presume it did not fit into any of the other diagnostic codes in ICPC-2.

The diagnoses associated with anxiety, depression or stress-related diagnoses in our study are similar to Kjeldsberg et al., who studied self-reported symptoms among patients in general practice (257). Moreover, these patterns of symptoms were similar in their findings independent of the diagnosis given (257). Among the most frequently reported symptoms are tiredness, musculoskeletal pain and headache in the population (258, 259) and general practice (103, 260). This result points to an interesting phenomenon of identifiable “clusters” of symptoms, which has not been studied much in general practice (261, 262).

Fatigue was significantly associated with an acute stress reaction, feeling depressed, anxiety disorder and depressive disorder. Fatigue in association with mental health disorders has also been found in other studies from primary care (132, 263-265).

Musculoskeletal pain was associated with several of the included psychological diagnoses. The relationship between pain, anxiety and depression has been found in other literature from general practice (138, 266).

Several psychological diagnoses were associated with diagnoses of digestive health problems, although nausea and constipation were only associated with depressive disorders and not anxiety disorders. Haug et al., in a Norwegian population study from 2002, found the opposite results: nausea and constipation were more strongly associated with anxiety disorders than depressive disorders (267). Autonomic gastric motility dysfunction has been found in major depression (268). Urinary incontinence was only associated with anxiety and not with depression. Felde et al. found that urinary incontinence was associated with anxiety and depression in a Norwegian population study from 2017 (269).

5.2.3 Paper III

We found a clear dose-response relationship between increasing levels of mental distress among patients and the probability of a diagnosis for the patients in our study. This indicates that the severity of distress affects GPs recognition, which has also been found in other studies (202). The probability of being recognized with a diagnosis also increased with an increasing number of consultations with a GP. Patients with the highest levels of distress had more consultations with their GP regardless of whether they had received a diagnosis. This is coherent with other literature from general practice (156-158).

There is a possibility for significant underdiagnosis amongst the participating GPs, as one in four patients with high levels of distress were not recognized. This underdiagnosis may be affected by patient factors, such as non-disclosure, or GP factors, such as clinical negligence. It is also possible that mental distress has been disclosed and addressed in consultations, but GPs have not registered this distress as a P-diagnosis in their patient’s electronic medical records. Literature shows that GPs do not always register a diagnostic code even though mental health problems have been described in free text (48). In addition, GPs do not always make a diagnosis even though mental health problems are discussed (205, 208).

There are fewer studies addressing GPs' recognition of mental distress than for distinct mental health disorders for us to compare our results. Yagil et al. performed a similar study in Israel, as they invited both patients and GPs to score patients' levels of mental distress after consultation. They found that GPs' assessments were only moderately associated with patients' distress but increased for GPs who were better at taking the patients' perspective (198). Greer et al. explored the GPs detection rate of patients' mental distress and found a sensitivity of 51 % and a specificity of 71 % in their material, a result interpreted as moderate at best (193). Bushnell et al. found that for patients with a diagnosable mental health disorder, GPs had identified psychological symptoms in 65 % of patients during the previous year. This increased to 80 % for patients with five or more consultations with a GP that previous year (158). These results were comparable to ours.

Comparing our results to studies addressing distinct mental health disorders, most often depression, our results are comparable to Berardi et al., who found that GPs identified 80 % of patients with depression. Ani et al. found that 75 % of patients were recognized with depression (184). We did not find studies with findings significantly higher than ours, and most other studies on recognition and diagnosis amongst GPs found lower levels of identification than we did.

There were a slightly higher number of women in the high-distress group, and they had a slightly higher number of somatic symptom diagnoses than patients who reported low levels of mental distress. Age or sex was not a significant factor for being recognized with a P-diagnosis in the adjusted analyses in our material.

The main strength of this study is that we could connect self-reported mental distress in patients with their complete electronic medical records from 12 months before and nine months after the questionnaire study, including all contacts and all diagnoses.

This gives a comprehensive picture of these patients’ contact with their GP over time. The main limitation of this study is that we could not collect data on the patients’ declining participation, limiting our information on response rate and comparability between the patients who wanted to participate and those who chose not to.

Distinctions between “normal” mental distress and psychiatric disorders are not always clear-cut; they depend on how these disorders are conceptualized for both patients and doctors (214, 270). Some patients without diagnoses may not want to be treated for mental health problems (271). Patients may not have disclosed their mental distress when consulting with their doctor, perhaps due to the potential stigma or fear of consequences (212, 219). After all, stigmatizing views are still found to be common among GPs (233). These factors limit our ability to evaluate in detail the degree of underdiagnosis by GPs in this study.

5.3 Methodological considerations

5.3.1 Design

We wanted to determine associations between different groups of patients in our material, which makes a descriptive comparative design appropriate for our aim. The study design does not allow for causative conclusions regarding the observed differences and associations found in this thesis.

We hypothesized that we would find differences between different groups, but the direction of association is not hypothesized; what comes first, the somatic or the mental complaint? The increased number of visits or the psychological diagnosis? This was outside the scope of our thesis and, therefore, outside the choice of our analytic strategies.

5.3.2 Clinical cohort

Our clinical cohort was part of the baseline data in the main research project. It consisted of five variables: Age, sex, reimbursement codes, GP code, and ICPC-2 diagnostic codes given in a 12-month cohort of patients. From these five variables, we conducted Paper I and Paper II.

We did not have other information on the patients studied, such as socioeconomic factors, lifestyle factors or other variables that could have further described the patients in the material. This limits our ability to evaluate the external validity of the results presented. The data was gathered from first-contact primary care. We expect the population to be heterogenous, including all different health and social conditions. The GP office centres were situated in an urban environment, and the results regarding the prevalence of diagnoses may be transferable to similar urban environments with a similar primary health care system, such as other Scandinavian urban city areas.

Elements regarding somatic symptoms are more clinical and may, to a larger degree, be transferrable to patients in primary care.

We had a complete set of all registered patient contacts at six GP office centres for 12 months. GPs in Norway need to register each contact with tariffs and diagnostic codes, as it sets the basis for reimbursement from the government. The GPs risk routine evaluations and will be financially liable for any wrongdoing. As these tariffs are specific for different types of patient contacts, this was a highly reliable code for type of contact in our analyses. The ages and sex of the patients were extracted from their national identification number, which needs to be correctly registered in electronic medical records to connect to other IT services such as addresses and prescription registries. This results in a solid material with minimal inconsistencies, all elements providing a high internal validity in the data.

The internal validity would also depend on the software created to extract these data. This was done with repeated extractions, quality checking the data and performing necessary revisions along the way. The founder of the company, Mediata AS, who was responsible for extracting the data, is himself a GP with experience in extracting data from electronic medical data from primary care and GP's daily practice.

Our data included patients aged 16-65 at inclusion. The original lower age limit was 18 years but was reduced to 16 years to include additional information on adolescents, who were studied separately (272). The focus of the main study was on adult patients, as older patients and children are treated in separate sections in specialized health care services. The lower age limit for a geriatric patient is defined as 65 years, where the upper age limit was set. We do not have information about patients outside the age range.

We did not take the opportunity to address multimorbidity in the form of the prevalence of psychological diagnoses for patients with various chronic health conditions in our clinical cohort for Paper I. The hypothesis is that we would find an increased prevalence of psychological diagnoses in patients with chronic health conditions, as shown in other studies (273, 274). This would have added an important perspective to this thesis.

For Paper II, we did not adjust for diagnoses of physical health disorders relevant to the different somatic symptoms presented in our material. We chose to include specific diagnoses from the “disorder” section (70-99 per organ chapter in ICPC-2) to the list of somatic symptom diagnoses included in our study. These diagnoses comprised; Stomach function disorder, irritable bowel syndrome, vertiginous syndrome, elevated blood pressure (not including uncomplicated or complicated hypertension), neck syndrome, back syndrome without radiating pain, back syndrome with radiating pain, shoulder syndrome, tension headache and hyperventilation syndrome. In retrospect, these should not have been included as they are not a part of the symptom category sections as defined by ICPC-2.

5.3.3 Questionnaire study

All patients showing up in the waiting room for two consecutive weeks in each participating GP office centre were invited to participate in a questionnaire study and gave written consent to link questionnaire data with clinical cohort data both 12 months retrospectively and nine months prospectively from when the questionnaire study was performed. We did not register patients declining to participate; therefore, we could not calculate the response rate for the questionnaire study. This is a limitation. We could have counted each patient declining without registering age or sex, but it was not done. We were able to couple the responses from the participating patients with their clinical cohort data, thereby coupling information about patients' self-reported levels of mental distress with all contacts and diagnoses they had received in contact with their GP for 21 months. This gave valuable information, even if we had no information about those declining participation.

Initially, we performed analyses on the 12-month and nine-month periods separately, but the results were very similar for the two periods, and the tables became large and unmanageable to present. We ended up presenting results for the 21 months as one continuous time period. This is a finding in itself, perhaps mirroring the longitudinal nature of primary care and often the long-term duration of different mental health disorders. These results were not included in the final Paper III, but in retrospect, they could have been included, either in the main article or in the supplementary material.

We do not have information on the duration of the participating patient's mental distress, whether their levels of distress could be attributed to intercurrent social circumstances or be representative of more long-term mental health issues, even if patients are asked to score how they have felt during the last week (246). Bedford et al. raised the question of whether CORE not only measures participants' states during the last week but also touches upon more stable and long-term attitudes and traits (275).

There are several barriers to participation that may represent bias in the material. One such barrier is language. Our questionnaires were available in Norwegian and English. It is conceivable that patients with limited written Norwegian or English language skills would be more prone to decline participation. Another assumption would be that patients with pronounced mental distress will tend towards social isolation, avoid such exposure, and decline participation. On the other hand, patients with low mental distress and proficiency in reading Norwegian or English would be more prone to say yes to participation. This would skew our results towards lower levels of mental distress and fewer patients with limited written Norwegian or English among the participants.

The questionnaires were delivered anonymously by patients directly in locked mailboxes in the waiting rooms. This allowed patients to take the questionnaire with them and hand it in later. This provided safety for patients so that their information was handled securely. The consent form with personal information and questionnaire responses were kept in two separate mailboxes upon submission. The self-response format may have aided some in participation. Conducting the study inside patients' local GP offices could provide social pressure for participation. We chose to invite patients as they entered the office, which provided time for patients to participate before appointments with a GP, or while waiting for family members.

Being asked deeply personal questions regarding their mental health may have influenced what patients chose to address in conversation with their GP, especially if they had an appointment shortly afterwards. GPs may also have been sensitized knowing a research project addressing patients' mental distress was conducted during the two weeks. Both elements would skew in the direction of increased recognition of patients with mental distress with a psychological diagnosis.

CORE-10 was our screening tool for mental distress (246). This validated measurement tool in wide international use makes the results transferrable to other literature. However, it does not identify any specific mental health disorder. We have studied the identification of mental distress by GPs in the form of a diagnostic code. This conclusion can not be made directly. A strength of the ICPC-2 classification system is that it includes symptom codes and codes for non-specific mental health problems, which may lower the threshold for a GP in providing a psychological code without the stigma of a mental health disorder.

The issue of diagnosis of mental health disorders is complex. Should all patients scoring high on mental distress, as reported for one week, receive a psychological diagnosis by their GP? Much information in consultation between a doctor and a patient is not captured by looking at diagnostic codes alone. Non-disclosed or nonidentified mental distress is not included, and mental distress not diagnosed by a GP is not included, even if such topics may have been discussed.

We can assume there will be individual differences in how GPs utilize the different diagnostic codes for their patients. For example, how quickly will a GP change a diagnostic code from the usual initial contact, which we now know is usually some somatic symptom complaint, to diagnostic codes covering potential underlying psychological reasons for patients' distress? Will GPs use a diagnostic code if patients show even pronounced symptoms of mental distress if this distress is related to concrete but passing external circumstances such as losing a job or getting a divorce from their spouse? This is not known, although we know GPs do not always set a psychological diagnosis when encountering mental health problems in their patients (208). Still, looking at diagnosis as a latent variable for identification, we are still able to find useful information by studying patterns with associations and differences between groups.

It is not recommended to include questionnaires with less than 90 % of responses included. This amounts to less than nine completed items in CORE-10. After our Paper III was submitted for publication, this was clarified in an updated version. This recommendation is partly based on CORE-10 being used to evaluate the effect of treatment. We included nine participants with less than nine items filled. Of these, six responded to eight items, two responded to seven items, and two responded to six items. Two of these nine participants had received a psychological diagnosis. These patients were still included, a limitation in our study, although not thought to have affected the conclusions presented significantly, due to the low number of incomplete responses.

5.4 Ethical considerations

We could extract data from electronic medical records without informed individual consent from participants in the clinical cohort, as described in the Ethics and Approvals chapter in this thesis. This furthers some consideration.

The argument that we should be able to conduct research from primary care in line with research that retrieves data from hospitals and other healthcare services without individual patient consent is strong. There should not be a differential treatment between general practice and other areas of medical research. To do this, we needed to retrieve data securely and safeguard all patients' privacy. The principal investigator coupled the data and provided each participant with a code number. The researchers received de-identified data, including only the allocated variables necessary to carry out their respective analyses.

We were conscious that the questionnaire included a question on suicidal thoughts. Exposing patients to deeply personal questions about their mental distress, including suicidality, without a secure support system available is an ethical issue. Still, we conducted the study inside a GP office with assumed possibilities for patients to address these issues with their GP if needed.

We went back into the data and reported the number of patients with a high score on the suicidality item, found the proportion that had been identified with a P-diagnosis, and reported this in the results section in Paper III.

Conclusions

Nearly one in five patients had received a mental health diagnosis during the year. Depression and anxiety were the most common diagnoses in our material, which is coherent with other literature from general practice and the population in general. Patients with mental health diagnoses had a significantly higher number of consultations with a GP regardless of age, sex, and reason for contact, which is also coherent with other literature. The patients who visited their GP most frequently were found to have a significant increase in the probability of having a mental health diagnosis.

Patients with common mental health diagnoses had a significant increase in the number of somatic symptom diagnoses. This included all the mental health diagnoses studied separately for both sexes and most age groups. The probability of having a mental health diagnosis increased with increasing somatic symptom diagnoses. We found the same symptoms being most significantly associated with having a mental health disorder with small variations, including fatigue, dizziness, headache, stomach and musculoskeletal pain, autonomous symptoms, incontinence, and irregular menstruation.

We found a clear association between the level of patient-reported mental distress and the probability of having received a mental health diagnosis. The probability increased with increasing levels of mental distress in a dose-response fashion. Still, only three in four patients with high levels of mental distress had received a mental health diagnosis from their doctor. The probability increased with an increasing number of consultations, and patients who reported high levels of mental distress had more frequent consultations with a GP, regardless of having a mental health diagnosis.

Implications

Conducting high-quality diagnostic studies on the prevalence of mental health disorders in general practice is costly and demands significant resources. It is important to be wary of the different measurement tools and diagnostic classification systems used in conducting this research in a primary care setting. Conducting studies using electronic medical data retrieved securely is helpful in increasing our knowledge of the prevalence of mental health disorders in primary care. There needs to be an infrastructure available for that to take place, as has been developed recently in Norway (276).

Many people in society are mainly healthy and rarely need to see their GP. Moreover, when they do, it may be for specific individual concerns that may not require substantial, comprehensive approaches to receive adequate care for their particular health need. The results in this thesis showed that patients with mental health diagnoses, and those who reported high levels of mental distress, had significantly increased levels of contact with their doctor and higher levels of somatic symptoms addressed by their GP. Furthermore, the patients who were the most frequent attenders had a substantial increase in the probability of having been given a mental health diagnosis by their GP.

This group of patients may need a more comprehensive address of their health and person to be and feel adequately cared for in the health care system. The patients with the most extensive health care needs require longer consultations, at least some of the time, and to develop a trusting relationship with their GP. The GPs need time and resources to study these patients' medical records, evaluate possible previous or ongoing trauma histories and reflect on their patient's overall health situation to provide a comprehensive approach to their patient's general physical and mental health needs. This is challenged by the increasing workload amongst GPs in Norway and other countries such as the UK (77, 277).

How we understand a patient's bodily and mental distress will affect how we categorize symptoms. We tend to see what we look for in our clinical evaluations. In essence, two classification systems have arisen: somatoform disorders in psychiatry, and functional disorders, in medicine, with little cross-reference to each other. What labels GPs put on their patients dictate where they will be referred and treated in specialized healthcare, with a risk of fragmented care and overuse of healthcare services.

Appropriately identifying a patient’s primary health concerns requires adequate diagnostic labels. Still, our focus on diagnoses may be too restrictive in primary mental health care. For example, we may need to use more continuous than categorical labels for levels of disability, trauma experiences, and multimorbidity. When addressing a patient's symptoms and concerns, GPs also need to address the relational and social aspects of a patient’s history.

We need classification systems in general practice that consider the level of human suffering in society. After all, the most significant factors affecting mental health lie outside the GPs office. The relational, economic, political, and societal aspects of our lives are far more critical in influencing why we end up feeling depressed, stressed, and hopeless. But we also need approaches to mental health care in primary care that can aid GPs in adequately identifying the patients that need to be referred further to other specialized mental health care services.

The goal should be that we, as GPs, can create a safe and healing space for patients to make sense of their symptoms and suffering when they need us the most. However, unfortunately, the minimal funds spent on academic research in general practice severely limits our possibilities of providing the knowledge needed for these needs to be appropriately addressed and implicated in daily general medical health care.

In her article titled “Interpretive medicine. Supporting generalism in a changing primary care world. " Joanna Reeve states that a clinical discipline should not be defined by the body of knowledge it owns but by how it uses its knowledge (17). She argues that family medicine needs to be understood as an intellectual discipline with important interpretive aspects. We need a theory of the self that integrates all these perspectives and provides a frame of reference in which patients can understand and make sense of their often complex combinations of symptoms, disease, and life circumstances as they present in primary care (17).

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RESEARCH ARTICLE

OPEN ACCESS

Prevalence and distribution of psychological diagnoses and related frequency of consultations in Norwegian urban general practice

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ABSTRACT

Objective: To investigate the prevalence and distribution of psychological diagnoses made by general practitioners (GPs) in urban general practice and the related frequency of consultations during 12 consecutive months in Norwegian general practice.
Design: A cross-sectional study with data extracted from 16,845 electronic patient records in 35 urban GP practices
Setting: Six GP group practices in Groruddalen, Norway.
Subjects: All patients aged 16–65 with a registered contact with a GP during 12 months in 2015.
Main outcome measures: Frequency and distribution of psychological diagnoses made by GPs, and the number of patients' consultations.
Results: GPs made a psychological diagnosis in 18.8% of the patients. The main diagnostic categories were depression symptoms or disorder, acute stress reaction, anxiety symptoms or disorder and sleep disorder, accounting for 67.1% of all psychological diagnoses given. The mean number of consultations for all patients was 4.09 (95% CI: 4.03, 4.14). The mean number of consultations for patients with a psychological diagnosis was 6.40 (95% CI: 6.22, 6.58) compared to 3.55 (95% CI 3.50, 3.51) ($p<0.01$) for patients without such a diagnosis. Seven percent of the diagnostic variation was due to differences among GPs.
Conclusions: Psychological diagnoses are frequent in urban general practice, but they are covered using rather few diagnostic categories. Patients with psychological diagnoses had a significantly higher mean number of GP consultations regardless of age and sex.
Implications: The knowledge of the burden of psychological health problems in general practice must be strengthened to define evidence-based approaches for detecting, diagnosing and treating mental disorders in the general practice population.

KEY POINTS

- Eighteen percent of patients aged 16–65 in our study of patients in urban general practice received one or more psychological diagnoses in 12 months.
- Depression was the most common diagnosis; followed by acute stress reaction, anxiety and sleep disturbance.
- Patients with psychological diagnoses had a significantly higher mean number of consultations compared to patients without such diagnoses regardless of age and sex.

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General practice; general urban practice; mental health; psychological diagnoses; ICPC-2; frequency of consultations

Introduction

Mental disorders are among the most common chronic health disorders worldwide [1]. These patients have lower life quality, lower life expectancy and higher disability-adjusted life years compared to the general population [2–5]. This poses a burden on health- and welfare systems, especially on the primary health care services where most of these disorders are treated [6,7]. Studies show a varying prevalence of mental disorders in general practice both in urban, suburban and rural settings. A large Danish study found that general practitioners (GPs) classified 11% of their patients with psychological problems [8]. A Spanish study found that the 12-month prevalence of any mental disorder in general practice was 23% [2]. A questionnaire survey with over 2000 participants

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from general practice in Belgium found a mental disorder in 42.5% of all patients, although only 5.4% of the patients consulted their doctor for mental health problems [9].

Patients with mental disorders seem to contact their GP more often than patients without such disorders [10,11]. However, studies on the impact of mental health problems on GPs' workload are few and show varying results. A Norwegian study based upon direct observation in urban general practice found that about every fourth of primary care consultations deals with a psychological problem [12]. A Danish study found that 2% of the working-age population contacted their GP during a six-month period for psychological stress [13].

There have been concerns that current research and treatment models for mental disorders do not adequately address the complex challenges of mental illness as it is presented in general practice [14] and there have been suggestions to move into more collaborative-type care models [15].

Aim

In this study, we wanted to investigate the scope of GP's work with mental disorders by studying the prevalence and distribution of GP assessed psychological diagnoses and the related frequency of consultations in a Norwegian urban setting. We wanted to assess if patients with psychological diagnoses consult more frequently compared to patients without such diagnoses, and how these matters vary with patients' age and sex, and between individual GPs.

Materials and methods

Design

A cross-sectional study during 12 consecutive months.

Setting

The recruitment was part of a larger cluster-randomized controlled study; Shared Care and Usual Health Care for Mental and Comorbid Health Problems [16]. For this study, we recruited two GP office centers each from three boroughs Grorud, Stovner and Alna in Groruddalen in Oslo, Norway. The recruitment followed the principles of availability sampling and the order of invitation was by equality in size between the boroughs (offices with 4–6 GPs were prioritized before offices with one, two or more than six GPs). The centers were contacted by telephone, followed by a visit including several members of the research group to introduce the project. The GPs would then decide on participation before signing a detailed contract. Nine GP office centers were contacted before six agreed to participate.

Data

Norwegian GPs record all medical contacts electronically, in order to obtain reimbursement in a government-aided tariff system. The International Classification of Primary Care 2 (ICPC-2) is used for diagnosis coding [17]. ICPC-2 divides into chapters that cover medicine at large, where chapter 'P – psychological' – consists of 26 codes for mental health complaints and 17 codes for psychiatric diagnoses. In this article, the term 'psychological diagnoses' covers all of these diagnostic codes. Outcome measures were psychological diagnoses made by the participating GPs during the 12 months period, as well as the number of consultations for their patients with or without such diagnoses. The electronic medical records from 17,973 patients and 111,870 contacts were extracted. Of these, 16,845 patients had one or more consultations with their GP, either in the form of office- or home visit. These accounted for 68,814 contacts during the 12 months, and these form the sample used in this study. The remaining excluded contacts were either a phone call, letter, prescription or interdisciplinary meetings. Contacts without a registered ICPC-2 diagnostic code were excluded.

Data collection

We extracted data from all contacts by all patients between 16 and 65 years of age seen by any of the participating GPs during 12 consecutive months in 2014 and 2015. There were no exclusion criteria. Variables extracted were age, sex, date of contact, type of contact, ICPC-2 diagnoses and reimbursement codes. A computer program was developed by the firm Mediata AS for this project to extract data from the different electronic medical records in the GP office centers.

Data analyses

Descriptive statistics in the form of frequencies (*n*) and percentages (%) were used to explore the distribution of psychological diagnoses. The number of consultations was described by means and standard deviations (mean ± SD). Differences in the mean number of consultations between participants with and without psychological diagnoses were analyzed using the independent *t*-test. Binary responses relating to whether a patient was given a psychological diagnosis or not by their GP were analyzed using a binary logistic regression model. In particular, we used the multilevel binary logistic regression to account for data clustering at the GP level. We obtained estimates of odds ratios (ORs) and their 95% confidence intervals from the model that was adjusted for patients' age and sex. In addition, we also obtained an estimate of the intracluster correlation (ICC) from the adjusted model. Here, the ICC described the variation in giving a psychological diagnosis that was attributable to differences between the GPs. All analyses were performed using Stata SE 15 (StataCorp, College Station, TX) and IBM SPSS Statistics 25 (Armonk, NY) and the significance level was set at $p=.05$.

Ethics

The project was approved by the Regional Committee on Medical and Health Research Ethics Health Region South East (reg. no. 2014/435), by the National Committee on Medical and Health Research Ethics (reg. no. 2014/160) and by the Data Protection Officer at Akershus University Hospital, Oslo (reg. no. 13/138).

Results

Patient characteristics

There were 9613 (57%) women and 7237 (43%) men in the sample. Mean age for the whole sample was 40.13 (95% CI: 39.93, 40.34) years, 39.90 (95% CI: 39.63, 40.16) years for women and 40.45 (95% CI: 40.13, 40.77) years for men. Women accounted for 42,992 (62.5%) and men 25,822 (37.5%) of the consultations.

GP characteristics

There were 35 GPs included in this study. Eighteen were women and 17 were men. The mean age for the whole group was 50.43 (95% CI: 46.84, 54.01). Mean age for women was 49.93 (95% CI: 44.94, 53.73) years and for men 51.59 (95% CI: 45.38, 57.79) years. There were 28 (80.0%) specialists in family medicine and seven (20.0%) non-specialists; 15 of the 18 women (87.5%) and 13 of the 17 men (76.8%) were specialists.

Psychological diagnoses

Of the 68,814 consultations, 9582 resulted in psychological diagnosis, accounting for 13.9% of the total number of consultations. The women had 5947 (62.1%) and men 3635 (37.9%) of the consultations resulting in psychological diagnosis, and this accounted for 16.1% and 16.4% of the total number of consultations for women and men, respectively.

18.8% of the patients received one or more psychological diagnoses (Table 1). There were 588 patients with two psychological diagnoses, 162 with three, 27 patients with four, four patient with five and one patient with six different psychological diagnoses given during the 12 months.

The ICPC-2 diagnostic codes divide between symptom categories (P01–P29) and disease categories (P70–P99). Symptom diagnoses alone were given to 48.4% of the patients, disease diagnoses alone were given to 37.0% of the patients, and both symptom and disease diagnoses were given to 14.5% of the patients.

Depression was the most common diagnosis. Depressive disorder (P76) and depressive symptoms (P03) together accounted for 27.9% of all diagnoses given. Acute stress reaction (P02) was the second-largest diagnosis with 14.9% of diagnoses given. Anxiety disorder (P74) and anxiety symptoms (P01) together accounted for 13.5%, and sleep disturbance (P06) accounted for 10.8% of the total psychological diagnoses given.

Number of consultations

The number of consultations during the 12 months ranged from 1 (4373 patients) to 86 (one patient). The mean number of consultations per patient was 4.09 (95% CI: 4.03, 4.14). The mean number of consultations for women was 4.47 (95% CI: 4.39, 4.55) and for men 3.57 (95% CI: 3.49, 3.65) (Figure 1). The mean number of consultations for patients with a psychological diagnosis was 6.40 (95% CI: 6.22, 6.58) and for patients without such a diagnosis 3.55 (95% CI 3.50, 3.51) (Table 2).

There were 2388 (14.2%) of patients with eight or more consultations during the 12 months. The probability of having a psychological diagnosis in this group was 41.2%, compared to 15.1% ($p<0.01$) for patients with less than eight consultations.

The top 10% of attenders (1 902) accounted for 23,909 (34.7%) of the consultations, with 12.57 (95% CI: 12.36, 12.78) mean number of consultations,

Table 1. Distribution of 4176 ICPC-II psychological diagnoses (mental health complaints and psychological diagnoses) in 3162 patients aged 16–65 years during 12 months.

ICPC-2 code	Diagnosis	Women, *N* (%)	Men, *N* (%)	Sum, *N* (%)
P01	Feeling anxious/nervous/tense	138 (3.30)	70 (1.68)	208 (4.98)
P02	Acute stress reaction	463 (11.09)	158 (3.78)	621 (14.87)
P03	Feeling depressed	164 (3.93)	86 (2.06)	250 (5.99)
P04	Feeling/behaving irritable/angry	2 (0.05)	2 (0.05)	4 (0.10)
P05	Senility feeling/behaving old	1 (0.02)	4 (0.10)	5 (0.12)
P06	Sleep disturbance	262 (6.27)	187 (4.48)	449 (10.75)
P07	Sexual desire reduced	0 (0.00)	4 (0.10)	4 (0.10)
P08	Sexual fulfillment reduced	1 (0.02)	50 (1.20)	51 (1.22)
P09	Sexual preference concern	2 (0.05)	4 (0.10)	6 (0.14)
P10	Stammering/stuttering/tic	2 (0.05)	3 (0.07)	5 (0.12)
P11	Eating problem in child	2 (0.05)	0 (0.00)	2 (0.05)
P15	Chronic alcohol abuse	17 (0.41)	51 (1.22)	68 (1.63)
P16	Acute alcohol abuse	1 (0.02)	2 (0.05)	3 (0.07)
P17	Tobacco abuse	32 (0.77)	51 (1.22)	83 (1.99)
P18	Medication abuse	16 (0.38)	11 (0.26)	27 (0.65)
P19	Drug abuse	11 (0.26)	46 (1.10)	57 (1.36)
P20	Memory disturbance	35 (0.84)	29 (0.69)	64 (1.53)
P22	Child behavior symptom/complaint	4 (0.10)	5 (0.12)	9 (0.22)
P23	Adolescent behavior symptom/complaint	1 (0.02)	3 (0.07)	4 (0.10)
P24	Specific learning problem	5 (0.12)	9 (0.22)	14 (0.34)
P27	Fear of mental health disorder	2 (0.05)	4 (0.10)	6 (0.14)
P28	Limited function/disability	4 (0.10)	2 (0.05)	6 (0.14)
P29	Psychological symptom/complaint other	208 (4.98)	125 (2.99)	333 (7.97)
P70	Dementia	6 (0.14)	4 (0.10)	10 (0.24)
P71	Organic psychosis other	1 (0.02)	1 (0.02)	2 (0.05)
P72	Schizophrenia	28 (0.67)	57 (1.36)	85 (2.04)
P73	Affective psychosis	39 (0.93)	21 (0.50)	60 (1.44)
P74	Anxiety disorder/anxiety state	228 (5.46)	126 (3.02)	354 (8.48)
P75	Somatization disorder	16 (0.38)	9 (0.22)	25 (0.60)
P76	Depressive disorder	612 (14.66)	304 (7.28)	916 (21.93)
P77	Suicide/suicide attempt	2 (0.05)	1 (0.02)	3 (0.07)
P78	Neuraesthenia/surmenage	9 (0.22)	1 (0.02)	10 (0.24)
P79	Phobia/compulsive disorder	40 (0.96)	25 (0.60)	65 (1.56)
P80	Personality disorder	14 (0.34)	23 (0.55)	37 (0.89)
P81	Hyperkinetic disorder	29 (0.69)	34 (0.81)	63 (1.51)
P82	Post-traumatic stress disorder	59 (1.41)	59 (1.41)	118 (2.83)
P85	Mental retardation	28 (0.67)	26 (0.62)	54 (1.29)
P86	Anorexia nervosa/bulimia	6 (0.14)	1 (0.02)	7 (0.17)
P98	Psychosis NOS/other	10 (0.24)	13 (0.31)	23 (0.55)
P99	Psychological disorders, other	29 (0.69)	36 (0.86)	65 (1.56)

Table 2. Mean number of consultations according to sex and age group, with or without a psychological diagnosis in 16,845 patients aged 16–65 years during 12 months.

	Overall		Mental health diagnosis		No mental health diagnosis		
	N	Mean ± SD	*N*	Mean ± SD	*N*	Mean ± SD	*p* Value*
Sex							
Female	9613	4.47 ± 4.06	1915	6.95 ± 5.38	7698	3.86 ± 3.40	<0.01
Male	7232	3.57 ± 3.61	1247	5.55 ± 5.38	5985	3.16 ± 3.21	<0.01
Age groups							
16–24	2680	2.70 ± 2.49	373	4.47 ± 3.74	2307	2.42 ± 2.08	<0.01
25–34	3648	4.09 ± 3.91	648	6.28 ± 5.50	3000	3.62 ± 3.29	<0.01
35–44	3797	4.17 ± 3.78	767	6.47 ± 4.74	3030	3.59 ± 3.25	<0.01
45–54	3576	4.47 ± 4.24	758	6.83 ± 5.11	2818	3.83 ± 3.73	<0.01
55–65	3144	4.72 ± 4.30	616	7.06 ± 5.67	2528	4.15 ± 3.67	<0.01

*Unadjusted *p* values (mean difference in visits for patients with vs. without psychological diagnoses).

compared to the bottom 90% with 44,905 (65.3%) of the consultations and 3.01 (95% CI: 2.97, 3.04) mean number of consultations. The probability of having a psychological diagnosis among the top 10% of attenders was 43.3%, compared to 15.7% for the bottom 90% of attenders ($p<0.01$).

Variation in probability for psychological diagnoses

The patients visited with their own assigned GP in 70.2% of the consultations. The remaining 31.5% were with other doctors at their GP office center, such as

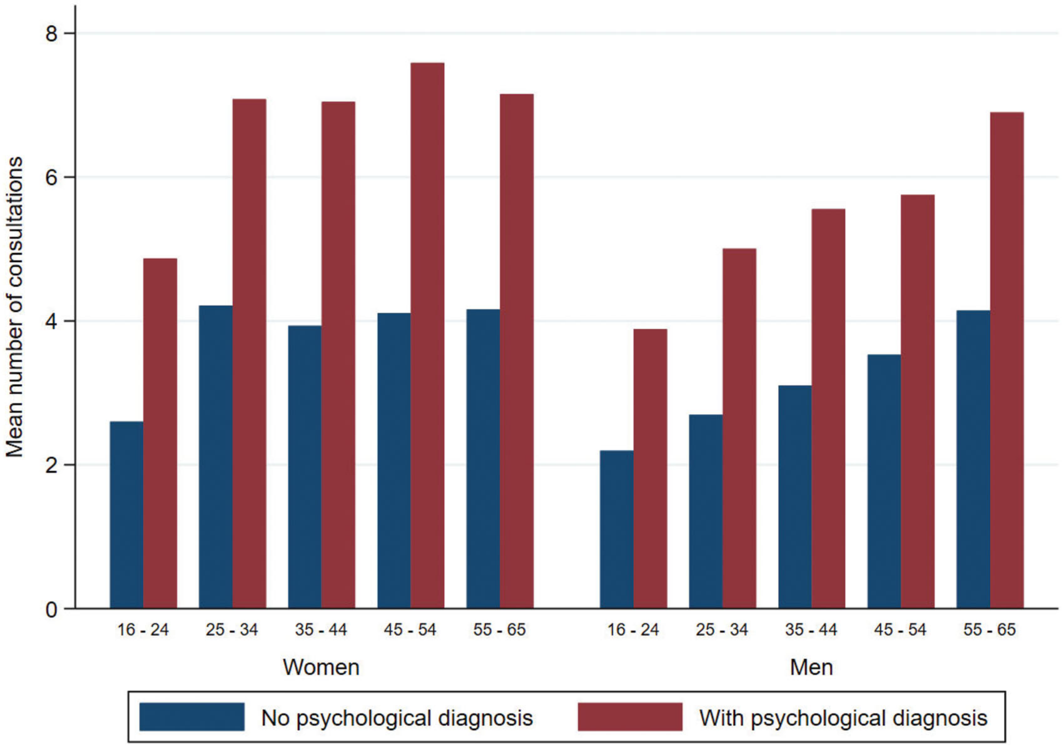

Figure 1. The mean number of consultations according to sex and age group for 16,845 patients aged 16–65 years with or without a psychological diagnosis during 12 months.

Table 3. Estimates of ORs and their 95% CIs obtained from the multilevel binary logistic regression showing the association between patient factors and having a psychological diagnosis given.

	Unadjusted		Adjusted	
Covariates	OR (95% CI)	*p* Value	OR (95% CI)	*p* Value
Age groups (ref: 16–24)				
25–34	1.34 (1.16, 1.53)	<0.01	1.32 (1.15, 1.52)	<0.01
35–44	1.57 (1.37, 1.79)	<0.01	1.56 (1.36, 1.78)	<0.01
45–54	1.66 (1.45, 1.91)	<0.01	1.67 (1.46, 1.91)	<0.01
55–65	1.51 (1.31, 1.73)	<0.01	1.51 (1.31, 1.73)	<0.01
Sex (ref: women)				
Men	0.84 (0.77, 0.91)	<0.01	0.83 (0.77, 0.90)	<0.01

other GPs, substitutes or interns. Including only consultations between patients and their assigned GP, these accounted for 14,111 patients, 8160 (57.8%) women and 5951 (42.2%) men. The probability for a psychological diagnosis was 18.6% among this subgroup, 19.7% for women and 18.6% for men.).

Table 3 shows the odds of receiving a psychological diagnosis from a GP by patient sex and different age groups. Overall, the odds of receiving a psychological diagnosis were significantly higher by increasing age group compared to the 16–24 age group, with 32% in the 25–34, 56% in the 35–44, 67% in the 45–54 and 51% in the 55–65 age groups, respectively. Men were 17% less likely to receive a psychological diagnosis than women were.

The results of a two-way interaction between sex and age groups are presented in Figure 2. The results showed that both women and men in older age groups were more likely to receive a psychological diagnosis than patients in the age group 16–24. Overall, a woman was 48% and men 56% more likely to receive a psychological diagnosis compared to the respective 16–24 age groups.

We obtained an ICC estimate of 0.074 from the adjusted multilevel logistic regression model. This means that 7.4% of the variability of the psychological diagnoses can be attributed to differences between the GPs.

Discussion

Summary of findings

Eighteen percent of patients in our sample received one or more psychological diagnoses during the 12 months. Fourteen percent of the consultations resulted in psychological diagnosis. Depression symptoms or disorder (P03, P76) were the biggest diagnostic categories, followed by acute stress reaction (P02), anxiety symptoms or disorder (P01, P74) and sleep

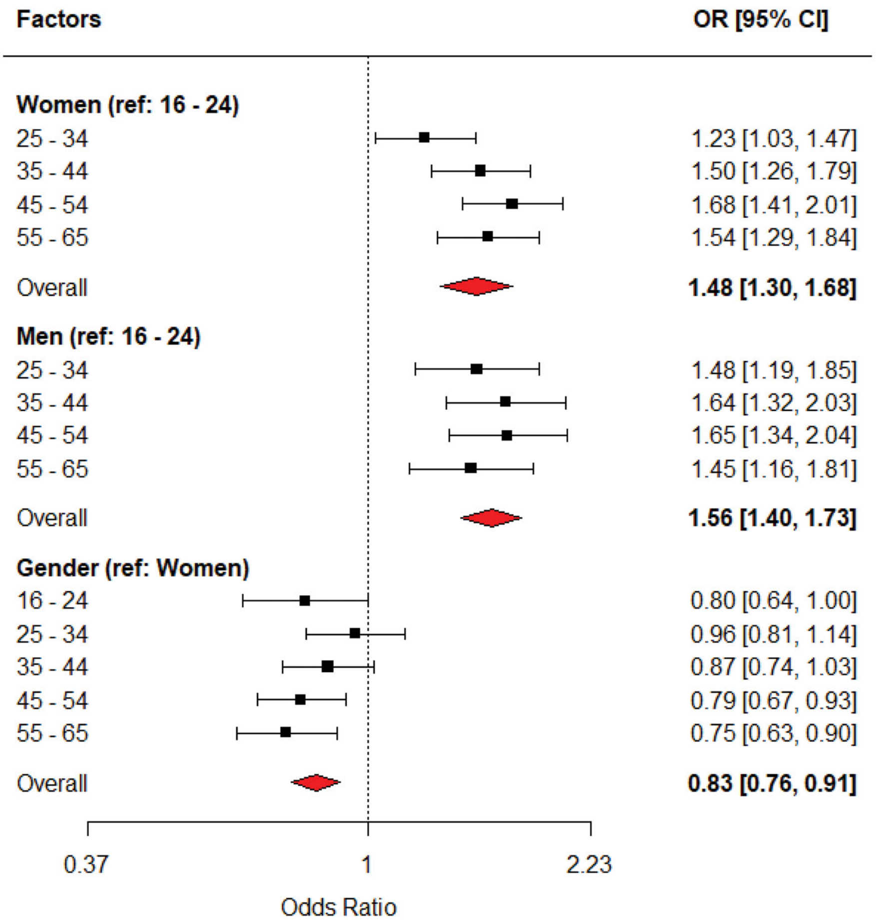

Figure 2. Odds of receiving a psychological diagnosis as a function of sex and age groups for 16,845 patients aged 16–65 years with or without a psychological diagnosis during 12 months.

disturbance (P06). These six diagnostic categories covered 67.1% of all the diagnoses given.

Patients who received a psychological diagnosis had a significantly higher number of consultations than patients without such a diagnosis ($p<0.001$). The probability of a psychological diagnosis increased with the number of consultations. Little over 7% of the variability of the psychological diagnoses were attributed to differences between individual GPs. The odds for a psychological diagnosis was higher for the women than the men in the sample, and the odds for psychological diagnosis for the whole sample increased with increasing age.

Discussion of results and existing literature

A report from Statistics Norway in 2017 showed psychological diagnoses to be the most frequent, with 12% of all diagnoses given to patients in Norwegian general practice [18]. This is similar but somewhat lower than in this study. The numbers from Statistics Norway are a national registry, includes all age groups, also children, and they only include the first registered diagnosis from each consultation with the GP. We know that GPs often register more than one diagnosis during each consultation, in our material, we have included all the diagnoses given during each consultation, and the study is performed in an urban setting.

The majority of psychological diagnoses in the material were captured using just a few diagnostic categories. This corresponds well with a Danish study that found that two problems (depression and acute stress reaction) accounted for 51% of all psychological classifications made in Danish general practice [8]. Some argue that the established classification systems for mental health issues are not effective and do not improve outcomes in clinical practice [19]. This may be especially true in general practice [20] where mental health issues are common but not always labeled, due to mild or passing symptoms that may not develop into more severe mental illness [21,22].

Patients who received a psychological diagnosis had a mean of 6.4 consultations during the year, compared to 3.6 for patients without a psychological diagnosis. This is higher than the total Norwegian population with an average of 2.5 yearly consultations in the 16–66 year age group in 2017 [18]. This corresponds well with other literature showing that patients with mental health issues see their doctor more frequently than patients without these issues [10,11].

The number of female patients in the material is higher than male patients, and the women see their doctor more often than the men, which results in higher absolute numbers of psychological diagnoses, consultations and we also see a higher probability for a psychological diagnosis when visiting a GP compared to the men in this material.

Strengths and limitations

This is to our knowledge the first comprehensive study of all psychological diagnoses by GPs through 12 months in Norwegian urban general practice. We found robust trends in our results, with statistically significant variations between groups. As Norway is a country where 99% of the population are listed with a GP and less than 2% of the population change their GP during a year [23], as well as the fact that diagnoses are the basis for reimbursement for the GPs from the government, we can trust the data as reliable.

A limitation of our study is that the diagnoses itself will not give a comprehensive description of the mental health issues among patients. Sometimes, GPs will not recognize a patient's mental health problem [24,25]. We know that patients bring up several issues during their consultations and that GPs do not always put a psychological diagnosis to all the problems addressed during a consultation [17,20]. The GP may choose not to use psychological diagnoses, due to mild symptoms and expected swift recovery, or due to stigma towards these issues [21,26]. The chance of detecting mental illness is found to increase with the number of GP consultations the patient has [27,28] and with the degree of continuity in the doctor–patient relationship [29]. This limits the generalizability of the information. There is a risk that psychological distress has been addressed in addition to other issues without a diagnosis, leading to under-reporting.

Another limitation is the geographical area of recruitment from just three boroughs in Oslo, with its distinctive urban features, in this case including a high number of immigrants and low socio-economical features. This means the population may not be representative of the population of Norway as a whole. This study also addresses the adolescent and adult population of patients, not including children under the age of 16 or the seniors above 65. If the study included more rural areas of Norway the results could be more representative for the total population.

We lack contributing factors such as socioeconomic features, ethnicity, lifestyle, alcohol and other drug use (unless there is a diagnosis of these issues) and other variables that could have further described the patients with psychological diagnoses in the material.

Conclusions and implications

This study addresses the importance of studying psychological health problems in general practice, where the population is different from specialized health care. Patients often present complex issues or also distress in the early stages, and this will look different from traditional psychiatric illness in specialized mental health care. The knowledge of the burden of mental health problems in general practice must be strengthened to define evidence-based approaches for detecting, diagnosing and treating mental disorders in the general practice population.

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OXFORD

Epidemiology

Somatic symptoms and associations with common psychological diagnoses: a retrospective cohort study from Norwegian urban general practice

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Abstract

Background: Patients with mental health problems often present with somatic symptoms when visiting their general practitioner (GP). Somatic presentations may challenge correct diagnosing of mental health disorders in general practice, where most of these disorders are treated.

Objective: Explore the associations between common psychological diagnoses and somatic symptom diagnoses in Norwegian urban general practice.

Methods: A retrospective cohort study including electronic medical data from 15 750 patients aged 16–65 years from 35 GPs in six GP offices in Oslo, Norway, during 12 months in 2014–2015. We explored prevalences and associations between anxiety-, depression-, and stress-related diagnoses, and somatic symptom diagnoses.

Results: Patients with anxiety-, depression- and stress-related diagnoses had a mean number of 2.9±3.6 somatic symptom diagnoses during the 12 months, compared to 1.9±2.5 for patients without any psychological diagnoses ($P < 0.001$). The mean number of somatic symptoms was significantly higher for the different psychological diagnoses viewed separately, for both sexes and different age groups. There was an increase in probability for anxiety, depression, or stress-related diagnoses with an increasing number of somatic symptom diagnoses during the 12 months. We found a significant increase in somatic symptom diagnoses from ICPC-2 chapters: General and unspecified, digestive, cardiovascular, musculoskeletal, neurological, urological, female genital disorders and social problems. Associated symptom patterns were different for each of the included psychological diagnoses.

Conclusions: This study shows that patients with anxiety, depression- and stress-related diagnoses present with increased and characteristic somatic symptoms compared to patients without these diagnoses in general practice.

Lay summary

Patients in general practice often present with diffuse and unexplained symptoms that are not always easily separated into mental or physical categories. In this study, we found that

Key Messages

- Anxiety was associated with digestive, musculoskeletal and urological symptoms.
- Depression was associated with digestive, and musculoskeletal symptoms.
- Acute stress was associated with musculoskeletal, urinary and menstrual symptoms.
- PTSD was associated with musculoskeletal and neurological symptoms.
- Increasing somatic symptoms increased the probability of psychological diagnoses.

patients with anxiety-, depression- and stress-related diagnoses have more bodily symptoms than patients without these diagnoses. We observed different bodily symptom patterns for the various psychological diagnoses included in this study. Also, we found a higher risk of having a psychological diagnosis with increasing bodily symptoms.

Key words: Anxiety, depression, general practice, psychological stress, PTSD, somatic symptoms

Introduction

Patients in general practice often present with diffuse and unexplained symptoms that do not follow the body–mind division that characterizes the classifications of disease used in the health care system today (1). This makes general practice the ideal environment for exploring patients' undifferentiated symptoms and disease patterns, which could readily fit both somatic and mental categories (1).

Many general practitioners (GPs) perceive somatic symptoms as possible presentations of social or emotional distress (2), and generally find common symptoms and complaints meaningful to deal with (3). Still, somatic symptom presentations may present a challenge for diagnosing mental health disorders in general practice (4). A WHO study from primary health care in 14 countries found that 69% of patients fulfilling criteria for depression reported only somatic symptoms as the reason for their doctors' visit (5).

Extensive evidence suggests that mental health disorders are associated with somatic symptoms (6–8). This association seems to be bidirectional, with an undecided theory of causation (9). Some studies focus on mental health issues as precursors to somatic symptoms (10). Other studies have the opposite focus: That having somatic symptoms may increase the risk of developing mental health issues (11). Some studies focus on shared etiological factors that may independently cause the onset of mental health disorders and somatic health problems (12,13).

Most of the literature on the association of mental and somatic health problems in general practice focus on depression (14,15). There are fewer studies on anxiety and somatic symptoms in primary care settings (16), but some studies from the general population (17,18).

There is sparse literature on symptoms of stress and somatic symptoms in general practice. A Swedish study looked at the prevalence of perceived stress and associations with anxiety and depression in patients seeking primary care and found that two-thirds of the patients expressed increased stress levels, indicating a high degree of burnout (19). Another Swedish study looked at somatic symptoms among patients referred from primary health care or occupational health service centers for stress-related exhaustion. They found that 98% reported at least one somatic symptom, and 45% reported six symptoms or more (20).

Post-traumatic stress disorder (PTSD) is well known to be associated with somatic health problems (21), and this condition seems to be underdiagnosed in general practice (22). This condition has traditionally been seen in patients with severe traumatic life events, but studies show that non-traumatic life events can also generate PTSD symptoms (23). A systematic review on prevalence, detection and correlates of PTSD in primary care from 2016 found increased levels of somatic health problems among patients with PTSD (24).

This study aims to explore associations between depression-, anxiety- and stress-related diagnoses, and somatic symptom diagnoses in general practice. We seek to investigate the prevalence of somatic symptom diagnoses in patients with or without common psychological diagnoses, whether a higher burden of somatic symptom diagnoses increases the probability of having a psychological diagnosis, and how individual somatic symptom diagnoses correlate with depression-, anxiety- and stress-related diagnoses.

Methods

Design and setting

A retrospective cohort study, collecting data from six GP offices with 35 participating GPs from the boroughs of Grorud, Stovner, and Alna in Oslo, Norway. The recruitment of GPs was part of a more extensive cluster-randomized controlled study, Shared Care and Usual Health Care for Mental and Comorbid Health Problems (25). Descriptive characteristics regarding the participating patients, GPs and the mean number of visits are described in a previous publication (26).

Data collection

Data was collected in 2015 and included electronic medical records for all patients with registered contact with their GP 12 months retrospectively. Data from all patients aged 16–65 years were included. Data from all registered patient contacts were extracted, comprising consultations, home visits, phone calls, letters, prescriptions, or interdisciplinary meetings. There were no exclusion criteria. Variables extracted were age, sex, date of contact, type of contact, registered diagnoses and reimbursement codes.

Diagnostic codes

Norway has a primary care system where 99% of the population is listed with a regular GP, and less than 2% of the population trade their GP during a year (27). The GPs are funded through a government-aided tariff system, and registered contacts require a diagnostic code for the medical contact to be valid for reimbursement. The International Classification of Primary Care, 2nd edition

(ICPC-2) is the diagnostic coding system used in Norwegian general practice (28). ICPC-2 divides into chapters that cover medicine at large. The diagnostic codes consist of one letter and two digits. The letter indicates an organ system. The numbers 00–29 indicate symptom diagnoses, while 70–99 indicate disease diagnoses, although with some overlap. Although ICPC-2 was designed to capture both patient's reasons for encounter, primary care interventions and data ordering in an episode-of-care structure, these potentials are not utilized to a full extent today. The journal-systems require the GPs to insert the diagnostic codes relevant to each individual contact into their electronic medical records. There are no specific requirements for the duration of health issues before a diagnosis can be made. This is decided at the discretion of the GP.

Psychological diagnoses

The psychological diagnosis chapter in ICPC-2 aims to be a comprehensive collection of mental health problems presented in general practice, ranging from symptoms such as a reduced sexual desire to severe disorders such as schizophrenia. We focused on the most significant types of mental health problems based on the most commonly occurring diagnoses in our data set (26). These included anxiety-, depression- and stress-related diagnoses. The description of these ICPC-two diagnoses and their corresponding International Classification of Disease, 10th edition (ICD-10) diagnoses are described in more detail in Online Table 1 (29).

Somatic symptoms diagnoses

Somatic symptom diagnoses refer to all the symptom diagnoses (-00-29) from each ICPC-2 organ chapter. Additionally, we have included diagnoses representing functional syndromes or symptom clusters commonly associated with mental health disorders in the literature (30). These diagnoses comprise; stomach function disorder, irritable bowel syndrome, vertiginous syndrome, elevated blood pressure, neck syndrome, back syndrome w/o radiating pain, back syndrome with radiating pain, shoulder syndrome, tension headache and hyperventilation syndrome. The description of these ICPC-2 diagnoses and their corresponding ICD-10 diagnoses are described in more detail in Online Table 1.

Table 1 *Number of somatic symptom diagnoses for 15 750 patients aged 16–65 years in Norwegian general practice, stratified by patients with selected psychological diagnoses,[a] sex and age groups (2014–2015)*

	Total	Sex		Age groups (years)		
	N = 15 750	Women n = 9089	Men n = 6661	16–30 n = 4505	31–50 n = 7083	51–65 n = 4162
Patients without psychological diagnoses, total						
N	13 683	7698	5985	4028	6044	3611
S diagnoses, mean (SD)	1.9 (2.5)	2.1 (2.6)	1.5 (2.3)	1.6 (2.1)	2.0 (2.7)	1.9 (2.6)
Patients with psychological diagnoses, total[b]						
N	2067	1391	676	477	1039	551
S diagnoses, mean (SD)	2.9 (3.6)	3.1 (3.6)	2.4 (3.3)	2.2 (2.9)	3.1 (3.8)	3.0 (3.6)
P-value	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**
Feeling anxious/nervous/tense						
N	208	138	70	56	88	64
S diagnoses, mean (SD)	3.2 (3.7)	3.5 (3.9)	2.4 (3.3)	2.4 (3.2)	3.5 (4.0)	3.3 (3.8)
P-value	**<0.0001**	**<0.0001**	**0.003**	**0.005**	**<0.0001**	**<0.0001**
Acute stress reaction						
N	621	463	158	156	336	129
S diagnoses, mean (SD)	2.9 (3.7)	3.0 (3.6)	2.6 (4.0)	2.1 (2.3)	3.0 (3.8)	3.7 (4.5)
P-value	**<0.0001**	**<0.0001**	**<0.0001**	**0.030**	**<0.0001**	**<0.0001**
Feeling depressed						
N	249	164	85	72	117	60
S diagnoses, mean (SD)	3.2 (3.4)	3.5 (3.7)	2.6 (2.8)	2.6 (3.4)	3.2 (3.4)	3.8 (3.3)
P-value	**<0.0001**	**<0.0001**	**0.0002**	**0.0002**	**<0.0001**	**<0.0001**
Anxiety disorder						
N	352	227	125	84	176	92
S diagnoses, mean (SD)	2.8 (3.6)	3.1 (3.4)	2.4 (4.0)	2.0 (2.5)	3.0 (4.1)	3.2 (3.6)
P-value	**<0.0001**	**<0.0001**	**0.0003**	0.106	**<0.0001**	**<0.0001**
Depressive disorder						
N	914	611	303	192	460	262
S diagnoses, mean (SD)	2.8 (3.5)	3.2 (3.8)	2.0 (2.5)	2.3 (3.1)	3.1 (3.7)	2.8 (3.3)
P-value	**<0.0001**	**<0.0001**	**0.007**	**<0.0001**	**<0.0001**	**<0.0001**
Post-traumatic stress disorder						
N	118	59	59	11	73	34
S diagnoses, mean (SD)	3.1 (3.2)	3.6 (3.4)	2.5 (3.0)	2.6 (2.1)	3.6 (3.4)	2.1 (2.8)
P-value	**<0.0001**	**<0.0001**	**0.002**	0.118	**<0.0001**	0.695

The *P*-values were calculated by a generalized linear mixed model adjusting for cluster effect on center-level. The patients without a psychological diagnosis served as a reference for each selected psychological diagnosis group. Bold values denote statistical significance at the $P < 0.05$ level.

ICPC-2, The International Classification of Primary Care, 2nd edition; SD, standard deviation.

[a] P-diagnoses includes the ICPC-2 diagnoses P01, P02, P03, P74, P76, P82.

[b] A total of 2067 patients were registered with at least one of the six selected P-diagnoses. As some were registered with more than one P-diagnosis, the six groups' sum is higher (n = 2462) than the number of patients.

Data analyses

Numbers were presented as frequencies and percentages or means and standard deviations (SD) as appropriate. Generalized linear mixed models with random effects for centre adjusting for possible cluster effect due to the hierarchical structure in the data were estimated to perform the following analyses. The number of somatic symptom diagnoses (S-diagnoses) between the patients with and without any psychological diagnosis (P-diagnosis) was compared. Differences between patients with and without individual P-diagnoses were also assessed. This analysis was performed for all patients and stratified by sex and age groups (16–30, 31–50 and 51–65 years). The differences in the occurrence of S-diagnoses from different organ chapters and individual most prevalent diagnoses (present among at least 1% of patients with any of the included P-diagnoses), S-diagnoses between those with and without (any and individual) P-diagnoses were assessed. The association between the number of S-diagnoses and the probability for P-diagnosis was tested, and the results were illustrated graphically as probabilities with corresponding 95% confidence intervals (CI).

Statistical analyses were performed by SPSS v26 and SAS v9.4. All tests were two-sided. Benjamini–Hochberg procedure was applied to control the false discovery rate due to multiple testing. The *P*-values indicating significant results after this adjustment are enhanced with bold-face.

Results

Study sample

During the 12 months, 16 845 patients conducted 66 814 consultations with a GP, either in-office or home visits. The remaining contacts were either phone calls, letters, prescriptions, or interdisciplinary meetings and not included. A total of 560 patients received anxiety-related diagnoses, 1163 patients received depression-related diagnoses and 739 patients received stress-related diagnoses. There were 1095 patients with other psychological diagnoses, therefore not included, and 13 683 patients without any psychological diagnoses during the year. This resulted in 15 750 patients included in this study, of them 9089 women and 6661 men.

Distribution of somatic symptom diagnoses in patients with or without psychological diagnoses

The somatic symptom distribution ranged from one diagnosis in 4841 (29%) patients to 36 different diagnoses in one patient during the 12 months. Patients with a psychological diagnosis had a higher number of somatic symptoms with a mean (SD) of 2.9 ± 3.6 diagnoses, compared to 1.9 ± 2.5 for patients without any psychological diagnosis during the 12 months ($P < 0.001$) as presented in Table 1. We found a significant increase in the mean number of somatic symptom diagnoses for each psychological diagnosis viewed independently for both sexes and most age groups.

The probability for at least one psychological diagnosis increased significantly ($P < 0.0001$) with an increasing number of somatic symptoms. This probability was significantly different from zero already from one somatic symptom diagnosis during the 12 months. When the number exceeds 26, the probability for at least one psychological diagnosis was significantly higher than 0.5 and kept increasing (Fig. 1).

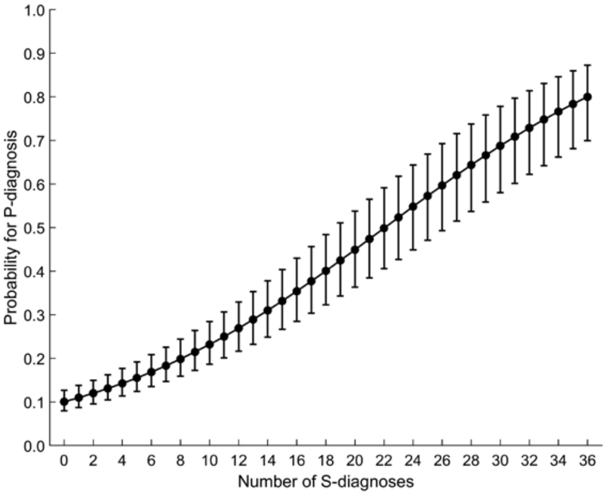

Figure 1 Probability for having anxiety-, depression- or stress-related diagnoses with an increasing number of somatic symptom diagnoses in 15 750 patients aged 16–65 years in Norwegian general practice from 2014 to 2015 (95% CI)

Somatic symptom diagnoses associated with psychological diagnoses

Table 2 shows the distribution of the most common somatic diagnostic codes stratified by patients with or without a psychological diagnosis, defined as diagnoses occurring in one percent or more of the psychological diagnoses group. Online Table 2 shows the complete list of the most commonly occurring individual diagnostic codes, whereas Table 2 shows only those with a significant difference between the two groups. Online Table 3 shows the association between the different psychological diagnoses and the different diagnostic chapters of the ICPC-2 classification system. Here, we see a significant increase in social problem–diagnoses for several of the psychological diagnoses. These are not represented in Table 2 or Online Table 3 as they occur in less than one percent of patients with psychological diagnoses overall.

Discussion

In this present study, we found a significant increase in somatic symptom diagnoses for any of the included psychological diagnoses, for both sexes and most age groups, compared to their corresponding group of patients without any psychological diagnoses. This is, to our knowledge, the first study to address individual psychological diagnoses and association with individual somatic symptoms in general practice and the first study to distinguish between psychological symptoms and disorders.

We found that the youngest age group showed a lesser increase in somatic symptoms than the other age groups. This was somewhat unexpected, as we know that adolescents also tend to present to their GP with somatic symptoms when they suffer from mental health problems (31). Their general health and functioning may be better due to their age; however, there are limitations when studying diagnoses alone. We know that mental health disorders tend to be underdiagnosed in general practice for all patients, especially young adults (31). Very few patients in this age group were diagnosed with PTSD, too few to find significant results.

We found an even increase in probability for having a psychological diagnosis through an increasing number of somatic symptom

Table 2. Distribution of diagnoses significantly associated with patients having a psychological diagnosis[a] in 15 750 patients aged 16–65 years from Norwegian general practice (2014–2015)

ICPC-2 Diagnoses *n* (%) *P*-value	Total *N* = 15750	Without psychological diagnosis *n* = 13683	With psychological diagnosis *n* = 2067	Feeling anxiety *n* = 208	Acute stress reaction *n* = 621	Feeling depressed *n* = 249	Anxiety disorder *n* = 352	Depressive disorder *n* = 914	PTSD *n* = 118
General weakness/ tiredness	946 (6.0)	752 (5.5)	194 (9.4) **<0.0001**	13 (6.3) 0.531	88 (14.2) **<0.0001**	30 (12.0) **<0.0001**	34 (9.7) **0.0006**	78 (8.5) **<0.0001**	5 (4.2) 0.575
General disease NOS	354 (2.2)	280 (2.0)	74 (3.6) **<0.0001**	8 (3.8) 0.057	16 (2.6) 0.583	14 (5.6) **0.0005**	18 (5.1) **0.0002**	28 (3.1) 0.017	4 (3.4) 0.274
General abdominal pain/cramps	749 (4.8)	596 (4.4)	153 (7.4) **<0.0001**	19 (9.1) **0.008**	43 (6.9) 0.022	22 (8.9) **0.010**	27 (7.7) **0.010**	76 (8.3) **<0.0001**	12 (10.2) **0.007**
Nausea	111 (0.7)	89 (0.7)	22 (1.1) 0.043	0 0.984	4 (0.6) 0.985	7 (2.8) **0.0002**	4 (1.1) 0.274	9 (1.0) 0.234	0 0.985
Constipation	116 (0.7)	85 (0.6)	31 (1.5) **0.0001**	3 (1.4) 0.194	9 (1.4) 0.034	8 (3.2) **<0.0001**	4 (1.1) 0.274	14 (1.5) **0.004**	1 (0.8) 0.804
Eye symptom/complaint	207 (1.3)	175 (1.3)	32 (1.5) 0.645	8 (3.8) **0.008**	11 (1.8) 0.433	1 (0.4) 0.188	2 (0.6) 0.216	15 (1.6) 0.704	3 (2.5) 0.313
Palpitations/awareness of heart	138 (0.9)	104 (0.8)	34 (1.6) **0.0001**	6 (2,9) **0.001**	6 (1.0) 0.556	3 (1.2) 0.420	5 (1.4) 0.172	18 (2.0) **0.0003**	2 (1.7) 0.261
Neck symptom/complaint	675 (4.3)	553 (4.0)	122 (5.9) **0.0007**	9 (4.3) 0.969	35 (5.6) 0.215	20 (8.0) **0.010**	21 (6.0) 0.099	60 (6.6) **0.0005**	5 (4.2) 0.975
Back symptom/complaint	834 (5.3)	698 (5.1)	136 (6.6) **0.004**	20 (9.6) **0.002**	47 (7.6) 0.028	10 (4.0) 0.529	21 (6.0) 0.316	58 (6.3) 0.058	7 (5.9) 0.642
Shoulder symptom/ complaint	590 (3.7)	500 (3.7)	90 (4.4) 0.164	7 (3.4) 0.801	32 (5.2) 0.230	14 (5.6) 0.183	9 (2.6) 0.260	52 (5.7) **0.0009**	2 (1.7) 0.264
Leg/thigh symptom/ complaint	222 (1.4)	189 (1.4)	33 (1.6) 0.528	2 (1.0) 0.572	9 (1.4) 0.868	10 (4.0) **0.003**	5(1.4) 0.993	12 (1.3) 0.901	1 (0.8) 0,612
Knee symptom/complaint	735 (4.1)	630 (4.6)	105 (5.1) 0.414	6 (2.9) 0.242	26 (4.2) 0.468	17 (6.8) 0.115	14 (4.0) 0.563	50 (5.5) 0.231	12 (10.2) **0.006**
Foot/toe symptom/ complaint	448 (2.8)	372 (2.7)	76 (3.7) 0.022	8 (3.8) 0.338	32 (5.2) **0.001**	7 (2,8) 0.979	8 (2.3) 0.587	32 (3.5) 0.179	2 (1.7) 0.490
Muscle pain	555 (3.5)	424 (3.1)	131 (6.3) **<0.0001**	15 (7.2) **0.002**	34 (5.5) **0.005**	10 (4.0) 0.395	22 (6.3) **0.001**	61 (6.7) **<0.0001**	10 (8.5) **0.002**
Back syndrome w/o radiating pain	424 (2.7)	355 (2.6)	69 (3.3) 0.083	8 (3.8) 0.335	17 (2.7) 0.834	14 (5.6) **0.003**	12 (3.4) 0.364	29 (3.2) 0.409	4 (3.4) 0.654
Shoulder syndrome	531 (3.4)	453 (3.3)	78 (3.8) 0.266	6 (2.9) 0.739	25 (4.0) 0.303	7 (2.8) 0.684	19 (5.4) 0.033	34 (3.7) 0.525	9 (7.6) **0.012**
Headache	610 (3.9)	492 (3.6)	118 (5.7) **<0.0001**	12 (5.8) 0.133	50 (8.1) **<0.0001**	15 (16.0) 0.069	22 (6.3) **0.013**	38 (4.2) 0.451	7 (5.9) 0.199
Vertigo/dizziness	431 (2.7)	355 (2.6)	76 (3.7) **0.008**	8 (3.8) 0.279	23 (3.7) 0.142	8 (3.2) 0.569	16 (4.5) 0.029	36 (3.9) 0.020	3 (2.5) 0.954
Tension headache	101 (0.6)	80 (0.6)	21 (1.0) 0.023	3 (1.4) 0.085	8 (1.3) 0.043	2 (0.8) 0.463	3 (0.9) 0.440	7 (0.8) 0.471	3 (2.5) **0.011**
Shortness of breath/ dyspnoea	153 (1.0)	121 (0.9)	32 (1.5) **0.005**	8 (3.8) **<0.0001**	10 (1.6) 0.067	6 (2.4) 0.016	3 (0.9) 0.949	12 (1.3) 0.190	1 (0.8) 0.966
Urine incontinence	86 (0.5)	60 (0.4)	26 (1.3) **<0.0001**	4 (1.9) **0.004**	9 (1.4) **0.0007**	3 (1.2) 0.083	5 (1,4) **0.011**	8 (0.9) 0.065	2 (1.7) 0.059
Menstruation irregular/ frequent	120 (0.8)	91 (0.7)	29 (1.4) **0.001**	3 (1.4) 0.206	11 (1.8) **0.003**	0 0.984	3 (0.9) 0.697	16 (1.8) **0.0008**	0 0.992
Breast symptom/ complaint	127 (0.8)	103 (0.8)	24 (1.2) 0.072	1 (0.5) 0.594	15 (2.4) **<0.0001**	2 (0.8) 0.993	2 (0.6) 0.658	8 (0.9) 0.836	1 (0.8) 0.943

The *P*-values were calculated by generalized linear mixed model adjusting for cluster effect on center-level. The patients without a P-diagnosis served as a reference for each selected P-group. Bold values denote statistical significance at the *P* < 0.05 level.

ICPC-2, The International Classification of Primary Care, 2nd edition; NOS, not otherwise specified; PTSD, post-traumatic stress disorder.

[a] P-diagnoses include the ICPC-2 diagnoses P01, P02, P03, P74, P76, P82.

diagnoses, which is in line with previous knowledge (32,33). We did not find any clear cut-off points. Somatic symptoms in general practice are so common (34) that GPs will have difficulties finding patients with undisclosed mental health problems based on the number of symptom diagnoses alone.

The diagnosis of fatigue was significantly increased for several different psychological diagnoses, which corresponds well with previous findings (8). Several psychological diagnoses were associated with diagnoses of digestive health problems, although nausea and constipation were only associated with depressive disorders and not anxiety disorders. A Norwegian population study from 2002 found the opposite results: nausea and constipation were more strongly associated with anxiety disorders than depressive disorders (35).

Urinary incontinence was only associated with anxiety and not with depression. A previous Norwegian population study found that urinary incontinence was associated with both anxiety and depression (36).

Strengths and limitations

The Norwegian government-aided tariff system, which makes the coding of ICPC-2-codes per contact fundamental, strengthens the data's comprehensiveness and diagnostic coding specificity. The GP office centers were recruited from Groruddalen in Oslo, a group of suburbs in an urban setting with a high number of first- or second-generation immigrants and general low socio-economic features. These elements will affect the generalizability of the study population. We only included patients from 16 to 65 years, excluding children and older adults/seniors. The rationale was that older patients and children would have features specific to their age groups, and we focused on adolescents and adult patients in this study.

This present study addresses associations and diagnostic patterns in a comprehensive group of GP patients during 12 months in general practice. It does not address causality issues nor chronological elements. There are several uncertainties associated with studying diagnoses in general practice. We know mental health disorders tend to be underdiagnosed (37). It often depends on how patients present their ailments to their doctor (5,38). We know that patients often raise several issues during a consultation (39), and we do not know how many of these issues would register with a diagnosis during the consultation. Although, a Norwegian study found that diagnoses in medical records correspond well with the content of consultations (40).

Conclusions

This study shows that patients with anxiety-, depression- and stress-related diagnoses present with increased and characteristic somatic symptoms compared to patients without these diagnoses in general practice. Increased knowledge on how different mental health symptoms and disorders present in general practice is essential. General practice can be an ideal environment to study the complex inter-relationship between somatic and psychological symptoms to better detect and treat mental health disorders in patients presenting with mixed symptoms and undisclosed mental health issues.

Supplementary material

Supplementary material is available at *Family Practice* online.

Declarations

Ethical approval: The project was approved by the Regional Committee on Medical and Health Research Ethics Health Region South East (reg.no 2014/435), by the National Committee on Medical and Health Research Ethics (reg.no 2014/160), and by the Data Protection Officer at Akershus University Hospital, Oslo (reg. no 13/138).

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Supplementary appendix

to the article

Somatic symptoms and associations with common psychological diagnoses. A retrospective cohort study from Norwegian urban general practice

By

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Oslo, Norway, 2021

Online Table 1 Description of all presented diagnoses from The International Classification of Primary Care, 2nd edition (ICPC-2)

Psychological diagnoses	
P01 Feeling of anxiety/nervousness/tension	Emotions that the patient conveys as an emotional or psychological experience and cannot be attributed to a mental disorder. Excludes: P74 Anxiety disorder. ICD-10: R45.0 Nervousness.
P02 Acute stress	A reaction to a stressful life event or a significant change in life that requires a major adjustment, either as an expected response to the event or as an inappropriate response that disrupts daily coping and results in impaired social function, with recovery over a limited period of time Excludes: P82 Post-traumatic stress disorder, P76 Depressive disorder ICD-10: F43.9 Reaction to severe stress, unspecified
P03 Feeling of depression	Emotions that the patient conveys as an emotional or psychological experience and cannot be attributed to a mental disorder Excludes P76 Depressive disorder ICD-10: R45.2 Unhappiness
P74 Anxiety disorder	Clinically significant anxiety that is not limited to specific environmental situations. It manifests as a panic disorder (recurrent bouts of severe anxiety that are not limited to particular situations, with or without physical symptoms) or as a disorder in which generalized and persistent anxiety, which is not limited to particular situations, occurs with various accompanying physical symptoms Excludes P01 Feeling of anxiety/nervousness ICD-10: F41.9 Anxiety disorder, unspecified
P76 Depressive disorder	Basic disorder in affect and mood swings towards depression. Mood, energy, and activity levels are simultaneously lowered, along with impaired ability to enjoy, feel interest, and concentrate. Sleep and appetite are usually disturbed, and self-esteem is impaired Excludes: P02 Acute stress reaction ICD-10: F32.9 Depressive episode, unspecified
P82 Post-traumatic stress disorder	A stressful life event followed by severe discomfort and disruption, with a delayed or prolonged reaction. This includes flashbacks, nightmares, emotional flattening, and anhedonia that inhibits social function and performance, and which includes decreased mood, anxiety, restlessness, and inability to cope, sustained over time. Excludes: P02 acute stress reaction ICD-10: F.43.1 Post-traumatic stress disorder

Somatic symptom diagnoses	
A04 Weakness/ tiredness general	Includes: Chronic fatigue, post-viral fatigue, fatigue, exhaustion, wear and tear Excludes: A05 Feeling ill, A29 General symptom/complaint other, A88 Adverse effect physical factor, P06 Sleep disturbance, P29 Psychological symptom/complaint other ICD-10: R53 Malaise and fatigue
A99 General disease NOS	Includes: Follow-up of problems NOS, disease carrier NOS ICD-10: R69 unknown and unspecified causes of morbidity
D01 Abdominal pain/ cramps general	Includes: Abdominal colic pain, abdominal cramps/discomfort/pain NOS Excludes: D02 Abdominal pain epigastric, D03 Heartburn, D06 Abdominal pain localized other, D07 Dyspepsia/indigestion, D08 Flatulence/gas/belching, X02 Menstrual pain, U14 Kidney symptom/complaint ICD-10: R10.4 Other and unspecified abdominal pain
D09 Nausea	Excludes: P16 Acute alcohol abuse, W05 Pregnancy vomiting/nausea, D02 Abdominal pain epigastric, D10 Vomiting, T03 Loss of appetite ICD-10: R11 Nausea and vomiting
D12 Constipation	Includes: Wedged or petrified stools Excludes: D99 Disease digestive system, other ICD-10: K59.0 Constipation
F29 Eye symptom/ complaint/other	ICD-10: H 57.9 Disorder of eye and adnexa, unspecified
K04 Palpitations/ awareness of heart	Includes: Bradycardia, tachycardia Excludes: K79 Paroxysmal tachycardia ICD-10: R00.2 Palpitations
L01 Neck symptom/complaint	Includes: Pain related to the cervical part of the spine/musculoskeletal system Excludes: N01 Headache, N03 Pain face ICD-10: M54.2 Cervicalgia
L02 Back symptom/complaint	Includes: Back pain NOS, thoracic back pain Excludes: L03 Low back symptom/complaint ICD-10: M54.9 Dorsalgia, unspecified
L08 Shoulder symptom/complaint	ICD-10: M25.5 Pain in joint

L14 Leg/thigh symptom/complaint	Includes: Leg/leg cramps Excludes: N04 Restless legs ICD-10: M79.6 Pain in limb
L15 Knee symptom/complaint	ICD-10: M25.5 Pain in joint
L17 Foot/toe symptom/complaint	Includes: Metatarsal pain ICD-10: M25.5 Pain in joint
L18 Muscle pain	Includes: Fibromyalgia, fibrositis, myalgia, panniculitis Excludes: L01 Neck symptom/complaint, L02 Back symptom/complaint, L03 Low back symptom/complaint, L14 Leg/thigh symptom/complaint ICD-10: M79.0 Rheumatism, unspecified
L84 Back syndrome w/o radiating pain	Includes: Degeneration in facet joints, back extension, collapsed vertebra NOS, spondyloarthritis/spondylosis of the spine, spondylolisthesis, spondylolysis Excludes: L03 Low back symptom/complaint, L86 Back syndrome with radiating pain. L83 Neck syndrome, P75 Somatization disorder, L86 Back syndrome with radiating pain ICD-10: M54.5 Low back pain
L92 Shoulder syndrome	Shoulder pain with restricted movement/local tenderness/crepitation; or periarticular calcifications in imaging Includes: rotator cuff syndrome, adhesion capsule in the shoulder/frozen shoulder, osteoarthritis/synovitis of the shoulder, shoulder bursitis, tendinitis around the shoulder ICD-10: M75.9 Shoulder lesion, unspecified
N01 Headache	Includes: Post-traumatic headache Excludes: N03 Pain face, N99 Neurological disease, other, R09 Sinus symptom/complaint, L83 Neck syndrome, N90 Cluster headache, N89 Migraine, S70 Herpes zoster, N95 Tension headache ICD-10: R51 Headache
N17 Vertigo/ dizziness	Includes: Feeling faint, loss of balance, instability Excludes: A88 Adverse effect, physical factor, H82 Vertiginous syndrome, A06 Fainting/syncope ICD-10: R42 Dizziness and giddiness
N95 Tension headache	Excludes: N90 Cluster headache, N89 Migraine ICD-10: G44.2 Tension-type headache
R02 Shortness of breath/dyspnoea	Excludes: R98 Hyperventilation syndrome, R03 Wheezing, R04 Breathing problem, other

	ICD-10: R06.0 Tension-type headache
U04 Incontinence urine	Includes: Enuresis of organic origin, stress incontinence, involuntary urination Excludes: P12 Bedwetting/enuresis ICD-10: R32 Unspecified urinary incontinence
X07 Menstruation irregular/frequent	Includes: Polymenorrhea Excludes: X06 Menstruation excessive ICD-10: N92.1 Excessive and frequent menstruation with an irregular cycle
X21 Breast symptom/ complaint other	Includes: Galactorrhea mastitis (not breastfeeding), mastitis (not breastfeeding), mastopathy Excludes: W94 Puerperal mastitis ICD-10: N64.9 disorder of breast, unspecified

ICPC-2: The International Classification of Primary Care, 2nd edition

ICD-10: International Classification of Diseases, 10th edition

NOS: Not otherwise specified

Online Table 2 Distribution of somatic symptom diagnoses in 15 750 patients aged 16-65 years with and without a P-diagnosis[1] in Norwegian general practice (2014-2015)

ICPC-2 Diagnoses **n (%)** **p-value**	**Total** **N=15750**	Without psychological diagnosis[1] **n=13683**	With psychological diagnosis[1] **n=2067**	Feeling anxiety **n=208**	Acute stress reaction **n=621**	Feeling depressed **n=249**	Anxiety disorder **n=352**	Depressive disorder **n=914**	PTSD **n=118**
Weakness/ tiredness general	946 (6.0)	752 (5.5)	194 (9.4) **<0.0001**	13 (6.3) 0.531	88 (14.2) **<0.0001**	30 (12.0) **<0.0001**	34 (9.7) **0.0006**	78 (8.5) **<0.0001**	5 (4.2) 0.575
Chest pain NOS	189 (1.2)	161 (1.2)	28 (1.4) 0.568	6 (2.9) 0.035	6 (1.0) 0.580	3 (1.2) 0.941	4 (1.1) 0.913	11 (1.2) 0.984	3 (2.5) 0.185
General symptom/ complaint/other	161 (1.0)	140 (1.0)	21 (1.0) 0.648	5 (2.4) 0.036	9 (1.4) 0.118	3 (1.2) 0.431	4 (1.1) 0.613	3 (0.3) 0.072	1 (0.8) 0.889
General disease NOS	354 (2.2)	280 (2.0)	74 (3.6) **<0.0001**	8 (3.8) 0.057	16 (2.6) 0.583	14 (5.6) **0.0005**	18 (5.1) **0.0002**	28 (3.1) 0.017	4 (3.4) 0.274
Abdominal pain/ cramps general	749 (4.8)	596 (4.4)	153 (7.4) **<0.0001**	19 (9.1) **0.008**	43 (6.9) 0.022	22 (8.9) **0.010**	27 (7.7) **0.010**	76 (8.3) **<0.0001**	12 (10.2) **0.007**
Abdominal pain epigastric	188 (1.2)	151 (1.1)	37 (1.8) **0.013**	6 (2.9) 0.021	12 (1,9) 0.085	4 (1.6) 0.471	7 (2.0) 0.131	13 (1.4) 0.389	1 (0.8) 0.795
Abdominal pain localized other	245 (1.6)	205 (1.5)	40 (1.9) 0.122	2 (1.0) 0.556	12 (1.9) 0.298	2 (0.8) 0.419	6 (1.7) 0.689	22 (2.4) 0.039	3 (2.5) 0.343
Nausea	111 (0.7)	89 (0.7)	22 (1.1) 0.043	0 0.984	4 (0.6) 0.985	7 (2.8) **0.0002**	4 (1.1) 0.274	9 (1.0) 0.234	0 0.985
Diarrhoea	233 (1.5)	195 (1.4)	38 (1.8) 0.110	6 (2.9) 0.047	15 (2.4) 0.100	5 (2.0) 0.331	7 (2.0) 0.333	9 (1.0) 0.329	2 (1.7) 0.755
Constipation	116 (0.7)	85 (0.6)	31 (1.5) **0.0001**	3 (1.4) 0.194	9 (1.4) 0.034	8 (3.2) **<0.0001**	4 (1.1) 0.274	14 (1.5) **0.004**	1 (0.8) 0.804
Eye symptom/ complaint/other	207 (1.3)	175 (1.3)	32 (1.5) 0.645	8 (3.8) **0.008**	11 (1.8) 0.433	1 (0.4) 0.188	2 (0.6) 0.216	15 (1.6) 0.704	3 (2.5) 0.313
Palpitations/ awareness of heart	138 (0.9)	104 (0.8)	34 (1.6) **0.0001**	6 (2,9) **0.001**	6 (1.0) 0.556	3 (1.2) 0.420	5 (1.4) 0.172	18 (2.0) **0.0003**	2 (1.7) 0.261
Neck symptom/complaint	675 (4.3)	553 (4.0)	122 (5.9) **0.0007**	9 (4.3) 0.969	35 (5.6) 0.215	20 (8.0) **0.010**	21 (6.0) 0.099	60 (6.6) **0.0005**	5 (4.2) 0.975

Back symptom/complaint	834 (5.3)	698 (5.1)	136 (6.6) **0.004**	20 (9.6) **0.002**	47 (7.6) 0.028	10 (4.0) 0.29	21 (6.0) 0.316	58 (6.3) 0.058	7 (5.9) 0.642
Low back symptom/complaint	726 (4.6)	621 (4.5)	105 (5.1) 0.479	9 (4.3) 0.672	29 (4.7) 0.883	5 (2.0) 0.027	17 (4.8) 0.992	52 (5.7) 0.215	8 (6.8) 0.292
Chest symptom/complaint	154 (1.0)	130 (1.0)	24 (1.2) 0.281	1 (0.5) 0.521	10 (1.6) 0.216	3 (1.2) 0.651	3 (0.9) 0.884	7 (0.8) 0.786	2 (1.7) 0.399
Shoulder symptom/complaint	590 (3.7)	500 (3.7)	90 (4.4) 0.164	7 (3.4) 0.801	32 (5.2) 0.230	14 (5.6) 0.183	9 (2.6) 0.260	52 (5.7) **0.0009**	2 (1.7) 0.264
Wrist symptom/complaint	124 (0.8)	101 (0.7)	23 (1.1) 0.122	1 (0.5) 0.635	9 (1.4) 0.100	1 (0.4) 0.499	6 (1.7) 0.053	8 (0.9) 0.718	2 (1.7) 0.262
Hand/finger symptom/complaint	183 (1.2)	153 (1.1)	30 (1.5) 0.338	6 (2.9) 0.037	7 (1.1) 0.830	1 (0.4) 0.540	8 (2.3) 0.080	13 (1.4) 0.518	0 0.986
Hip symptom/complaint	216 (1.4)	179 (1.3)	37 (1.8) 0.105	3 (1.4) 0.891	14 (2.3) 0.064	4 (1.6) 0.743	5 (1.4) 0.903	16 (1.8) 0.290	1 (0.8) 0.649
Leg/thigh symptom/complaint	222 (1.4)	189 (1.4)	33 (1.6) 0.528	2 (1.0) 0.572	9 (1.4) 0.868	10 (4.0) **0.003**	5(1.4) 0.993	12 (1.3) 0.901	1 (0.8) 0,612
Knee symptom/complaint	735 (4.1)	630 (4.6)	105 (5.1) 0.414	6 (2.9) 0.242	26 (4.2) 0.468	17 (6.8) 0.115	14 (4.0) 0.563	50 (5.5) 0.231	12 (10.2) **0.006**
Ankle symptom/complaint	157 (1.0)	128 (0.9)	29 (1.4) 0.119	5 (2.4) 0.066	6 (1.0) 0.895	5 (2.0) 0.166	3 (0.9) 0.798	16 (1.8) 0.037	3 (2.5) 0.109
Foot/toe symptom/complaint	448 (2.8)	372 (2.7)	76 (3.7) 0.022	8 (3.8) 0.338	32 (5.2) **0.001**	7 (2,8) 0.979	8 (2.3) 0.587	32 (3.5) 0.179	2 (1.7) 0.490
Muscle pain	555 (3.5)	424 (3.1)	131 (6.3) **<0.0001**	15 (7.2) **0.002**	34 (5.5) **0.005**	10 (4.0) 0.395	22 (6.3) **0.001**	61 (6.7) **<0.0001**	10 (8.5) **0.002**
Neck syndrome	222 (1.4)	190 (1.4)	32 (1.5) 0.396	4 (1.9) 0.440	6 (1.0) 0.434	3 (1.2) 0.979	8 (2.3) 0.136	15 (1.6) 0.381	2 (1.7) 0.738
Back syndrome w/o radiating pain	424 (2.7)	355 (2.6)	69 (3.3) 0.083	8 (3.8) 0.335	17 (2.7) 0.834	14 (5.6) **0.003**	12 (3.4) 0.364	29 (3.2) 0.409	4 (3.4) 0.654
Shoulder syndrome	531 (3.4)	453 (3.3)	78 (3.8) 0.266	6 (2.9) 0.739	25 (4.0) 0.303	7 (2.8) 0.684	19 (5.4) 0.033	34 (3.7) 0.525	9 (7.6) **0.012**
Headache	610 (3.9)	492 (3.6)	118 (5.7) **<0.0001**	12 (5.8) 0.133	50 (8.1) **<0.0001**	15 (16.0) 0.069	22 (6.3) **0.013**	38 (4.2) 0.451	7 (5.9) 0.199
Vertigo/ dizziness	431 (2.7)	355 (2.6)	76 (3.7) **0.008**	8 (3.8) 0.279	23 (3.7) 0.142	8 (3.2) 0.569	16 (4.5) 0.029	36 (3.9) 0.020	3 (2.5) 0.954
Tension headache	101 (0.6)	80 (0.6)	21 (1.0) 0.023	3 (1.4) 0.085	8 (1.3) 0.043	2 (0.8) 0.463	3 (0.9) 0.440	7 (0.8) 0.471	3 (2.5) **0.011**

Shortness of breath/dyspnoea	153 (1.0)	121 (0.9)	32 (1.5) **0.005**	8 (3.8) **<0.0001**	10 (1.6) 0.067	6 (2.4) 0.016	3 (0.9) 0.949	12 (1.3) 0.190	1 (0.8) 0.966
Cough	855 (5.4)	744 (5.4)	111 (5.4) 0.577	15 (7.2) 0.424	30 (4.8) 0.476	14 (15.6) 0.884	22 (6.3) 0.623	51 (5.6) 0.847	3 (2.5) 0.150
Throat symptom/complaint	486 (3.1)	414 (3.0)	72 (3.5) 0.364	9 (4.3) 0.368	18 (2.9) 0.868	11 (4.4) 0.285	17 (4.8) 0.081	34 (3.7) 0.327	6 (5.1) 0.228
Respiratory symptom/ complaint/other	321 (2.1)	276 (2.0)	45 (2.2) 0.933	5 (2.4) 0.990	19 (3.1) 0.034	3 (1.2) 0.243	8 (2.3) 0.895	15 (1.6) 0.153	2 (1.7) 0.702
Incontinence urine	86 (0.5)	60 (0.4)	26 (1.3) **<0.0001**	4 (1.9) **0.004**	9 (1.4) **0.0007**	3 (1.2) 0.083	5 (1,4) **0.011**	8 (0.9) 0.065	2 (1.7) 0.059
Contraception intrauterine	197 (1.3)	174 (1.3)	23 (1.1) 0.429	1 (0.5) 0.316	6 (1.0) 0.466	4 (1.6) 0.629	0 0.976	13 (1.4) 0.878	0 0.981
Contraception other	367 (2.3)	310 (2.3)	57 (2.8) 0.817	5 (2.4) 0.524	13 (2.1) 0.549	12 (4.8) 0.186	9 (2.6) 0.818	26 (2.8) 0.693	2 (1.7) 0.468
Pregnancy symptom/ complaint other	283 (1.8)	253 (1.8)	30 (1.5) 0.062	3 (1.4) 0.536	9 (1.4) 0.343	8 (3.2) 0.212	3 (0.9) 0.157	14 (1.5) 0.189	0 0.968
Menstruation irregular/frequent	120 (0.8)	91 (0.7)	29 (1.4) **0.001**	3 (1.4) 0.206	11 (1.8) **0.003**	0 0.984	3 (0.9) 0.697	16 (1.8) **0.0008**	0 0.992
Pelvis symptom/ complaint female	148 (0.9)	113 (0.8)	35 (1.7) 0.018	6 (2.9) 0.029	8 (1.3) 0.316	7 (2.8) 0.037	5 (1.4) 0.476	18 (2.0) 0.030	1 (0.8) 0.859
Breast symptom/ complaint other	127 (0.8)	103 (0.8)	24 (1.2) 0.072	1 (0.5) 0.594	15 (2.4) **<0.0001**	2 (0.8) 0.993	2 (0.6) 0.658	8 (0.9) 0.836	1 (0.8) 0.943

The p-values were calculated by generalized linear mixed model adjusting for cluster effect on centre-level. The patients without a P-diagnosis served as a reference for each selected P-diagnosis.

[1] P-diagnoses group includes the ICPC-2 diagnoses P01, P02, P03, P74, P76, P82

ICPC-2: The International Classification of Primary Care, 2nd edition; NOS: not otherwise specified; PTSD: post-traumatic stress disorder

NOS: Not otherwise specified

Online Table 3 Distribution of somatic symptoms from the different ICPC-2 chapters for 15 750 patients aged 16-65 years with and without a psychological diagnosis[1] in Norwegian general practice (2014-2015)

ICPC-2 Diagnoses **n (%)** **p-value**	**Total** **N=15750**	Without psychological diagnosis[1] **n=13683**	With psychological diagnosis[1] **n=2067**	Feeling anxiety **n=208**	Acute stress reaction **n=621**	Feeling depressed **n=249**	Anxiety disorder **n=352**	Depressive disorder **n=914**	PTSD **n=118**
A – General and unspecified	2095 (13.3)	1714 (12.5)	381 (18.4) **<0.0001**	39 (18.8) **0.004**	139 (22.4) **<0.0001)**	60 (24.1) **<0.0001**	67 (19.0) **0.0002**	146 (16.0) **0.0004**	18 (15.3) 0.325
B – Blood	51 (0.3)	43 (0.3)	8 (0.4) 0.576	1 (0.5) 0.637	4 (0.6) 0.171	2 (0.8) 0.187	0 0.991	1 (0.1) 0.309	0 0.991
D – Digestive	2021 (12.8)	1675 (12.2)	346 (16.7) **<0.0001**	38 (18.3) **0.012**	98 (15.8) 0.035	48 (19.3) **0.002**	65 (18.5) **0.001**	157 (17.2) **<0.0001**	23 (19.5) 0.021
F – Eye	446 (2.8)	372 (2.7)	74 (3.6) 0.055	14 (6.7) **0.002**	16 (2.6) 0.742	5 (2.0) 0.400	12 (3.4) 0.494	38 (4.2) 0.025	8 (6.8) **0.013**
H – Ear	397 (2.5)	333 (2.4)	64 (3.1) 0.075	5 (2.4) 0.978	14 (2.3) 0.771	6 (2.4) 0.979	18 (5.1) **0.002**	32 (3.5) 0.046	6 (5.1) 0.070
K – Cardiovascular	324 (2.1)	264 (1.9)	60 (2.9) **0.005**	8 (3.8) 0.048	16 (2.6) 0.253	6 (2.4) 0.560	13 (3.7) 0.022	26 (2.8) 0.062	3 (2.5) 0.625
L – Musculoskeletal	5243 (33.3)	4448 (32.5)	795 (38.5) **<0.0001**	76 (36.5) 0.318	234 (37.7) 0.036	94 (37.8) 0.173	135 (38.4) 0.029	359 (39.3) **0.0001**	52 (44.1) **0.011**
N – Neurological	1258 (8.0)	1015 (7.4)	243 (11.8) **<0.0001**	29 (13.9) **0.001**	86 (13.8) **<0.0001**	31 (12.4) **0.004**	48 (13.6) **<0.0001**	91 (10.0) **0.007**	15 (12.7) 0.033
R – Respiratory	1826 (11.6)	1561 (11.4)	265 (12.8) 0.132	38 (18.3) **0.005**	80 (12.9) 0.259	32 (12.9) 0.657	45 (12.8) 0.542	118 (12.9) 0.297	13 (11.0) 0.832
S – Skin	1297 (8.2)	1134 (8.3)	163 (7.9) 0.381	15 (7.2) 0.517	53 (8.5) 0,961	24 (9.6) 0.521	28 (8.0) 0.792	65 (7.1) 0.158	8 (6.8) 0.527
T – Endocrine/metabolic/ nutritional	125 (0.8)	103 (0.8)	22 (1.1) 0.059	0 0.994	7 (1.1) 0.220	0 0.998	4 (1.1) 0.330	11 (1.2) 0.076	1 (0.8) 0.871
U – Urological	417 (2.6)	328 (2.4)	89 (4.3) **<0.0001**	13 (6.3) **0.001**	26 (4.2) **0.006**	9 (3.6) 0.220	15 (4.3) 0.028	36 (3.9) **0.004**	5 (4.2) 0.202
W – Pregnancy	1193 (7.6)	1035 (7.6)	158 (7.6) 0.346	16 (7.7) 0.702	51 (8.2) 0.825	29 (11.6) 0.084	17 (4.8) 0.030	68 (7.4) 0.251	2 (1.7) 0.021

X – Female genital	987 (6.3)	809 (5.9)	178 (8.6) **0.001**	15 (7.2) 0.554	63 (10.1) **<0.0001**	26 (10.4) **0.008**	17 (4.8) 0.337	87 (9.5) **0.0001**	8 (6.8) 0.751
Y – Male genital	269 (1.7)	235 (1.7)	34 (1.6) 0.810	7 (3.4) 0.078	11 (1.8) 0.918	3 (1.2) 0.538	4 (1.1) 0.408	13 (1.4) 0.505	3 (2.5) 0.496
Z – Social Problems	101 (0.6)	63 (0.5)	38 (1.8) **<0.001**	2 (1.0) 0.258	13 (2.1) **<0.0001**	5 (2.0) **0.0004**	7 (2.0) **0.0001**	12 (1.3) **0.0003**	2 (1.7) 0.061

The p-values were calculated by generalized linear mixed model adjusting for cluster effect on center-level. The patients without a P-diagnosis served as a reference for each selected P-group.

[1] Psychological diagnoses include the ICPC-2 diagnostic codes; P01, P02, P03, P74, P76, P82

ICPC-2: The International Classification of Primary Care, 2nd edition; PTSD: post-traumatic stress disorder

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GPs' identification of patients with mental distress: a coupled questionnaire and cohort study from norwegian urban general practice

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Abstract

Background Mental health problems are one of the leading causes of disease burden worldwide, and are mainly diagnosed and treated in general practice. It is unclear however, how general practitioners (GPs) identify mental health problems in their patients. The aim of this study was to explore how patients' self-reported levels of mental distress correspond with psychological diagnoses made by their GPs, and associations with sex, age, number of consultations, and somatic symptom diagnoses.

Methods A questionnaire study coupled with retrospective and prospective cohort data from 553 patients aged 16–65 years in six GP offices in Oslo, Norway during 21 months in 2014–2016.

Results We found that 73.3% of patients with self-reported high levels of mental distress versus only 13.3% of the patients with low levels of mental distress had received a psychological diagnosis ($p < 0.01$). We found an increase in number of consultations for the group with high levels of mental distress regardless of having received a psychological diagnosis ($p < 0.01$). There was also an increase in number of somatic symptoms ($p = 0.04$) and higher number of females (0.04) in this group. 35% of patients had received one or more psychological diagnosis by their GP. Mean CORE-10 score, being female and a high number of consultations was associated with having received a psychological diagnosis. In the adjusted analyses high CORE-10 score and a high number of consultations still predicted a psychological diagnosis.

Conclusions We found a clear association between self-reported mental distress and having received a psychological diagnosis amongst the participants, and the probability for being identified increased with increasing levels of mental distress, and increasing number of visits to their doctor. This suggests that GPs can identify patients with high levels of mental distress in general practice in an adequate way, even though this can sometimes be a complex issue.

Trial registration Trial registration The main study was retrospectively registered in ClinicalTrials.gov on August 10 2019 with identification number NCT03624829.

Keywords General practice, Psychological distress, Mental health, Diagnoses

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Background

Mental health problems are one of the leading causes of disease burden worldwide [1]. These problems range from mild distress to severe psychiatric illness. How these patients are identified and what characterizes them is thus important to explore, so measures can be taken to provide adequate and high-quality care. General practice is usually the first point of contact with the health care system, and where the largest portion of these patients are treated [2, 3]. General practitioners (GPs) are therefore in a good position to provide health care to this group of patients.

Many studies over several decades have pointed towards GPs' lack of correctly identifying and treating mental health problems in their patients [4–9]. Most of these studies look at the extent to which GPs can diagnose defined mental illnesses, such as depression or anxiety disorders [10, 11]. Fewer studies have looked at how GPs identify general mental distress in their patients and we have not found any studies from within the last decade.

Mental distress refers to significant emotional upset that is common to a range of psychological and psychiatric conditions. A greater proportion of primary care patients suffer distress than suffer depression [6]. Recognition of mental distress is strongly associated with management and outcome [12]. Recognized as compared to non-recognized cases are more likely to receive adequate health care, and have better outcomes in terms of both mental health and social functioning [12]. The cost of failing to diagnose and treat mental health problems can be dramatic, as these issues result in increased utilization of health care and lower work participation [13–15].

Improving GPs' knowledge of their patients' histories and circumstances, as well as the patients' ability and space to communicate the entirety of their problems are crucial components of improving health care quality [4, 5, 16, 17]. Facilitating these elements within the time limits of a primary care setting and in a cost-effective manner would have an enormous impact on several levels of the health care system [18]. Some have proposed that psychosocial assessments should be integrated into routine primary care, and studies have shown that patients are positive towards this type of assessment intervention [18].

In this study, we wanted to explore whether self-reported mental distress amongst patients is related to the probability of having received a psychological diagnosis in consultation with a GP. We wanted to compare self-reported mental distress through a questionnaire survey, coupled with diagnostic data from electronic medical records from patients GPs. Finally, we wanted to explore whether patients' age, sex, number of consultations and number of somatic symptom diagnoses influenced on this probability of receiving a psychological diagnosis.

Methods

Study population and participants

This study is part of a larger research project: Shared Care and Usual Health Care for Mental and Comorbid Health Problems, a cluster-randomized controlled intervention study on the impact on patients and health care by a shared care between GPs and mental health care services [19–23]. This study is based on two datasets from the baseline data in the main project. Firstly, a questionnaire study was performed during two weeks in 2015 at six GP office centers in Groruddalen, Oslo, Norway. All patients aged 16–65 years entering the office centers during these two weeks were invited to fill in a questionnaire (CORE-10) before their appointment with a doctor. All participants were given written information about the one-page questionnaire, available in Norwegian and English. They gave written consent before participation. Secondly, we collected electronic medical records from all patients aged 16–65 from these office centers 12 months retrospectively and nine months prospectively from when the questionnaire study was performed. The prospective period could not be extended to 12 months as it would interfere with the intervention in the main study [19].

The upper age limit of 65 years was set as it is the lower age limit for geriatric patients, and they are followed up in separate departments in specialized mental health care and therefore not included in the main study.

In Norway, there is a system where all patients have the right to a GP according to a list system administered by the state through local municipalities. Over 99% of all Norwegian citizens are registered with a GP.

Questionnaire data

The questionnaire consisted of CORE-10, a comprised version of ten items on psychiatric symptoms drawn from the CORE-OM questionnaire, developed to measure mental distress for use in primary health care services [24, 25]. CORE-10 is evaluated as a reliable and valid instrument that is practical to use with people presenting with common mental health problems in primary care settings [25, 26]. We collected 845 questionnaires in total. Of these, 215 questionnaires were excluded as they were incomplete, or the patients were outside of the age range (16–65 at inclusion). Another 77 were excluded because of incomplete data or participants not being part of the cohort of registered patients at the offices. This left 553 questionnaires included in this study. This is presented in Fig. 1 in the Supplementary Material 1.

Table 1 Distribution of CORE-10 scores for 553 patients aged 16–65 in Norwegian general practice in 2015–2016

CORE-10 Score	Total n (%)	Men (%)	Women (%)
Healthy (0–5)	18 (3.3)	8 (4.7)	10 (2.6)
Low level problems (> 5–10)	102 (18.4)	36 (21.3)	66 (17.2)
Mild psychological distress (11–15)	202 (36.5)	61 (36.1)	141 (36.7)
Moderate distress (16–20)	141 (25.5)	43 (25.4)	98 (25.5)
Moderately severe (21–25)	67 (12.1)	17 (10.1)	50 (13.0)
Severe psychological distress (> 26–40)	23 (4.2)	4 (2.4)	19 (5.0)
SUM	553 (100.0)	169 (32.9)	384 (67.1)

Cohort data

Electronic patient records from all patients aged 16–65 years at inclusion were collected, 12 months retrospectively and later nine months prospectively from the time that the questionnaire study was performed. All registered contacts were included, as were age, sex, date of contact, type of contact, International Classification of Primary Care 2nd edition (ICPC-2) diagnoses [27], and tariffs (reimbursement codes) used by the GPs. A computer program was developed by the firm Mediata AS for this project to extract data from the different GP office centers. This included data from 16 845 patients with direct consultations with GPs. Phone contacts, prescriptions, meetings, and other types of contacts not specific to contact with a GP directly were not included. We coupled these cohort data to the questionnaire data for those patients participating in the questionnaire study and had given written consent. Later we extracted the same variables nine months prospectively, but now only for the patients included in the questionnaire study.

Data management

The questionnaire data and consent forms are kept in a safe server at Akershus University Hospital and the cohort data in a Service for Sensitive Data platform administrated by the University of Oslo.

Data analyses

For the “number of somatic symptoms” variable, we collected all symptom diagnoses (00–29) from the ICPC-2 chapters; General and unspecified, Digestive, Musculoskeletal, Neurological, and Social problems, and aggregated them, so each diagnosis given was registered only once. Descriptive statistics in the form of frequencies and percentages were used to describe categorical variables, whereas numerical data were described by means and standard deviations.

Mean differences between groups were accessed using the independent t-test, whereas associations between categorical variables were analyzed using a Chi-square test. We performed binary logistic regression looking at factors that were associated with having a psychological diagnosis. The variables used in the binary regression were; Age, sex, mean CORE-10 score, mean number of consultations and number of somatic symptom diagnoses. Each variable was analyzed adjusting for all the other variables in this group. All analyses were performed using STATA SE 16 (StataCorp, College Station, TX) and IBM SPSS Statistics 25 (Armonk, NY), and the significance level was set at $p=0.05$.

Results

Patient characteristics

A total of 553 patients were included in the study. Of them, 384 (69.4%) were women and 169 (30.6%) were men. The data collection process is presented in Fig. 1 in the Supplementary Material 1. Mean age for the whole group was 43.1 [95% CI: 41.9, 44.2] years, 42.0 [95% CI: 40.7, 43.4] years for women and 45.5 [95% CI: 43.4, 47.5] years for men. The patients included had 11.6±7.6 mean number of consultations with their GP during the period, 12.0±7.7 for the women, and 10.6±7.4 for the men.

The number of somatic symptom diagnoses ranged from zero (160 patients) to 11 (one patient), the mean number of somatic symptom diagnoses was 1.7±1.7, for the women 1.8±1.8, and 1.4±1.5 for the men.

Level of mental distress

The mean CORE-10 score for all patients was 14.8±5.6; the mean score for the women was 15.2 [95% CI: 14.6, 15.8], and the mean score for the men was 14.0 [95% CI: 13.1, 14.8]. Table 1 shows the distribution of CORE-10 scores in the sample.

Mental distress and GP assigned psychological diagnosis

We found a clear association between the level of self-reported mental distress and having received a psychological diagnosis amongst the participants. Figure 1 shows the marginal effects obtained from a binary logistical regression model describing the probability of having a psychological diagnosis with increasing CORE-10 scores for the participants in this study.

Of the patients with the highest levels of distress (CORE-10 score 21–40) ($n=90$), 74.3% had received a psychological diagnosis versus only 13.3% of the patients with low levels of distress (CORE-10 score 0–10) ($n=120$) ($p<0.001$). Comparing these two groups we found a

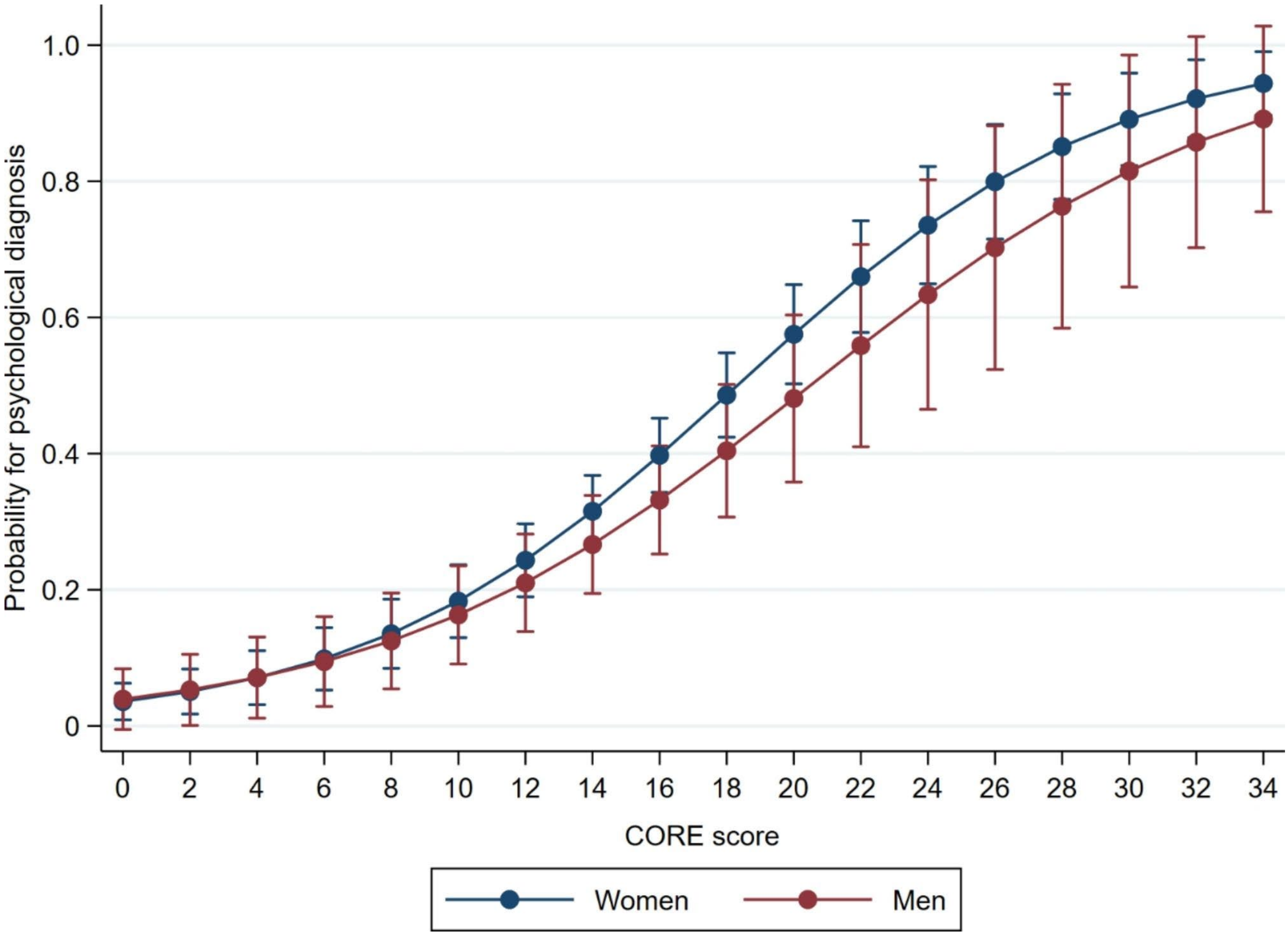

Fig. 1 Associations between psychological diagnosis and CORE-10 scores among 553 patients aged 16–65 years in Norwegian general practice in 2015–2016 (95% CI)

Table 2 Characteristics of 210 patients aged 16–65 years with severe versus low self-reported mental distress in Norwegian general practice

Covariates	Severe mental distress (CORE-10 scores 21–40)	Low mental distress (CORE-10 scores 0–10)	*P*-value
Sex: n (%)			0.04
Women	69 (32.9)	76 (36.2)	
Men	21 (10.0)	44 (21.0)	
Age (years): mean (SD)	44.7 (12.5)	42.3 (13.3)	0.81
Number of consultations: mean (SD)	15.9 (9.4)	9.10 (6.1)	< 0.01
Psychological diagnosis (%)	66 (73.3)	24 (13.3)	< 0.01
Number of somatic symptom diagnoses: mean (SD)	1.8 (1.7)	1.3 (1.5)	0.04

significant difference in the number of consultations ($p<0.01$), the number of somatic symptom diagnoses ($p=0.04$) with both being higher in the high levels of distress group as shown in Table 2. We found no significant differences in age, but being female was a significant factor (0.04) between the two groups.

Patient characteristics and probability of receiving a psychological diagnosis

35% of patients received one or more psychological diagnosis in the period, either as a symptom (152 patients), disorder (95 patients), or both (51 patients). Comparing patients with or without a psychological diagnosis in the material, we found that sex, mean number of consultations, and mean CORE-10 score was associated with having received a psychological diagnosis, as shown in Table 3.

The results of a binary logistic regression analysis looking at factors associated with having a psychological diagnosis are presented in Table 4. We found that mean CORE-10 score was still a highly significant factor ($p<0.01$) when adjusting for age, sex, number of consultations and number of somatic symptom diagnoses received. The number of consultations was still a highly significant factor ($p<0.01$) when adjusting for age, sex, mean CORE-10 score and number of somatic symptom

Table 3 Characteristics of 553 patients aged 16–65 years with or without a psychological diagnosis in Norwegian general practice in 2015–2016

Covariates	Psychological Diagnosis (n = 196)	No Psychological Diagnosis (n 357)	*P*-value
Sex: n (%)			0.04
Women	147 (26.6)	237 (42.9)	
Men	49 (8.9)	120 (21.7)	
Age (years): mean (SD)	43.4 (12.8)	42.9 (14.1)	0.63
Number of consultations: mean (SD)	14.3 (8.7)	10.1 (6.5)	< 0.01
CORE-10 score: mean (SD)	17.9 (5.7)	13.1 (4.8)	< 0.01
Number of somatic symptom diagnoses: mean (SD)	1.8 (1.9)	1.6 (1.6)	0.10

Table 4 Probability for a psychological diagnosis in 553 patients aged 16–65 years in Norwegian general practice in 2015–2016

Covariates	Unadjusted		Adjusted	
	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Sex (ref: Men)				
Women	1.52 (1.03, 2.25)	0.04	1.31 (0.84, 2.04)	0.23
Age in years	1.00 (0.99, 1.02)	0.64	0.99 (0.98, 1.01	0.37
Mean number of consultations	1.08 (1.05, 1.10)	< 0.01	1.07 (1.04, 1.11)	< 0.01
Number of somatic symptom diagnoses	1.09 (0.99,1.21)	0.08	0.95 (0.83, 1.08)	0.40
CORE-10 Clinical score	1.19, (1.15,1.24)	< 0.01	1.17 (1.12, 1.22)	< 0.01

diagnoses. When adjusting for mean CORE-10 score, number of consultations and age, sex (being female) was no longer a significant factor giving increased probability for a psychological diagnosis compared to males. These results presented as odds rations, show that each additional consultation and each unit increase in CORE-10 score significantly increased the likelihood of having a psychological diagnosis by 7% (OR 1.07) and 17% (OR 1.17) respectively.

The CORE-10 questionnaire has one item regarding suicidal thoughts (question 6: Do you have thought about ending your life?). Nine patients rated themselves as having these thoughts "most of the time", five of these had received a psychological diagnosis.

Discussion

We found a clear dose-response relationship between the level of self-reported mental distress and the probability of having received a psychological diagnosis by a GP amongst the participants. This is coherent with other literature [4, 28]. We also found that patients with higher levels of mental distress have more consultations than patients with low levels of mental distress, and the probability for having received a psychological diagnosis increased with the number of contacts, when adjusted for the level of mental distress, age, sex and number of somatic symptom diagnoses.

The strength of this study is that we were able to connect self-reported mental distress in patients with their full electronic medical records from 12 months before and nine months after the survey, including all contacts and all diagnoses. This gives a comprehensive picture of these patients' contact with their GP.

There are several limitations to this study. Mainly, we could only couple the cohort data to patients participating in the questionnaire study. We could not collect data on the other patients declining participation, therefore limiting our information on the comparability between the patients who wanted to participate and those who did not. All patients entering the doctors' offices during the 2 week inclusion period was invited to participate. We could have simply counted the patients declining, but we did not. There is a possible selection bias as the patients were recruited by the researchers in the waiting room before a doctor's appointment. We can theorize that patients with high levels of mental distress would be more likely to say "no" to participation, and patients with low levels of mental distress more likely to participate. This would skew our results in the direction of lower overall mental distress amongst the participants. This study was performed in three boroughs in Groruddalen in Oslo. These are suburbs with a high level of immigrants and low socioeconomic level compared to other areas of Oslo and Norway as a whole. We can also assume that patients with little Norwegian or English language skills would be more likely to decline participation, and therefore reduce the number of immigrant patients even though all information was available in English and Norwegian.

The CORE-10 questionnaires ask participants to include how they have felt the last week. We do not know their stress debut, duration, whether it was a short reactive state, related to a specific life event, or as a part of a larger psychiatric condition or other physical illness. We do not know whether patients were in early stages, or at the tail end of their illness and follow up. This is why we included a large cohort to explore patterns both before and after the survey was performed.

There are several factors to consider when exploring the complexities of psychological diagnosis in general practice. GPs are tasked with determining the nature of patients' mental distress and providing appropriate care. Sophisticated consulting skills are required to differentiate a wide range of symptoms from a complex narrative in a short amount of time, as the patient's experience and description of symptoms do not follow the body-mind divide that characterizes the classification of disease in the health care system today [29].

Distinctions between "normal" mental distress and psychiatric disorders are not always clear-cut; they depend on how these disorders are conceptualized, for both patients and doctors [16, 30]. Patients' specific beliefs about their presenting symptoms play an important role in predicting GPs' recognition and treatment of mental distress [4, 5]. Not all patients with less severe symptoms of psychological distress may want to or need to be treated [31]. Some patients may present symptoms due to short-term adjustment disorders that might not require intervention, but overlap with symptoms of mental disorders. Patients may disguise or underplay their symptoms because of the stigma of disclosure or differing beliefs about their presenting symptoms may affect how they are disclosed [4, 5, 32]. This is particularly apparent during initial visits to the GP before a trusting relationship has been established [32].

Patients tend to present with somatic presentations of mental distress in general practice [33]. Most GPs are cautious not to miss a life-threatening organic condition or serious somatic illness when presented with varying somatic symptoms [33]. They will tend to investigate somatic symptoms first, and risk becoming focused on possible organic disease instead of considering mental illness when patients present with somatic distress [29, 32].

What is the "gold standard" for diagnosing different mental health disorders in primary care? Different instruments for "screening" and diagnosing mental illness show differing results when compared [34]. There are also differing perspectives amongst GPs and psychiatric specialists in this area [35–40]. A Danish qualitative study from 2014 found that for depression, psychiatrists regarded the diagnosis as a pragmatic and agreed construct, and did not question its validity. GPs considered depression as more of a "gray area" and questioned the clinical utility in general practice. GPs were also more skeptical about instruments that they felt could be misleading [37]. For patients that present with symptoms that are perhaps not included as part of a psychiatric disorder, GPs may refrain from setting a psychiatric diagnosis, even when they suspect one [39, 41].

Increasing recognition of mental health problems does not necessarily correspond to better outcomes for patients, as increased recognition only helps if GPs and other parts of the health care system have the skills and resources to deliver adequate interventions once the patients are identified [42].

Conclusion

Our study shows that GPs are largely able to identify mental distress in patients, but there are many unknown factors when it comes to identifying mental distress and mental health problems in general practice still. We need further research as this group of patients and their care has such a large impact on our health care system.

List of abbreviations

CORE-10	Clinical Outcomes in Routine Evaluation 10.
GP	General practitioner.
ICPC-2	International Classification of Primary Care, 2nd edition.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12875-022-01865-x.

Supplementary Material 1

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Author contributions

TR is the project leader and was involved in forming the main research project. MPD, ORH, TR contributed to the planning and design of the main study. MPD analyzed and interpreted the patient data. MB has been the main supervisor throughout the article process. OR is a member of the research group and was involved in recruiting GP office centers. All authors read and approved the final manuscript.

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Data Availability

The datasets used and analyzed during this study are available from the project's principal investigator (TR) on reasonable request.

Declarations

Ethics approval and consent to participate

The project was approved by the Regional Committee on Medical and Health Research Ethics Health Region South East (reg.no 2014/435), by the National Committee on Medical and Health Research Ethics (reg.no 2014/160), and by the Data Protection Officer at Akershus University Hospital, Oslo (reg. no 13/138).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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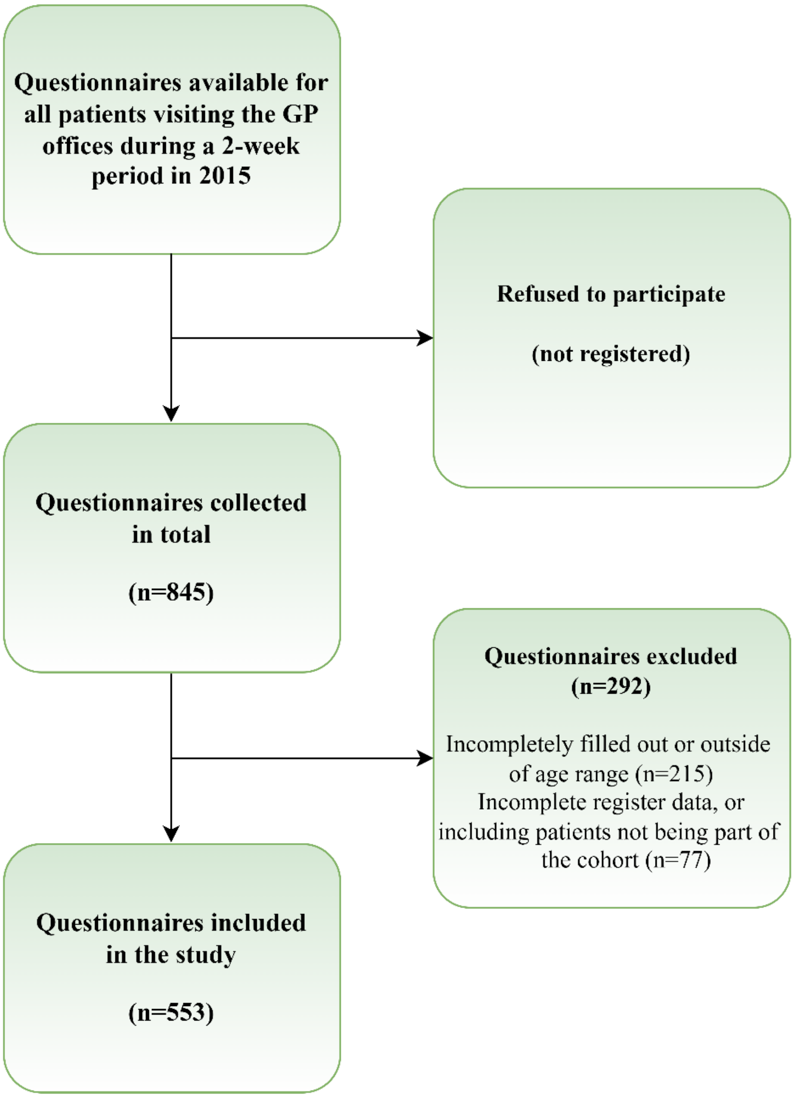
Publisher's Note

APPENDIX

Figure 1. Collection of questionnaire data for 553 patients in Norwegian general practice in 2015-2016



Du kan bidra ved å fylle ut et kort spørreskjema om din helsetilstand, og om helsetilbudet slik det er nå

Tverrfaglige helseteam kan sammen med fastlegen gi et utvidet helsetilbud knyttet til legesentre

- Slike helseteam skal prøves ut i Groruddalen
- Du kan bidra i forskningsprosjektet om helsetilbudet

Du deltar i studien ved å gjøre dette:

- Gi undertegnet samtykke til fastlegen eller legesekretæren
- Legg utfylt spørreskjema i konvolutt i boksen på venterommet

- Du kan ta med informasjonsarkene om du ønsker det
- Du får et kort spørreskjema om 3 måneder og 9 måneder

Akershus universitetssykehus

UNIVERSITETET I OSLO

Forespørsel om deltakelse i forskningsprosjektet: Samarbeid mellom fastleger og andre helsetjenester

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie som gjennomføres i bydelene i Groruddalen i 2015. Vi vil undersøke hvordan samarbeidet er mellom fastleger og andre helsetjenester er, og særlig hvordan psykiske helseplager eventuelt i kombinasjon med andre helseplager ivaretas. I en seinere del av prosjektet vil vi undersøke om et tett samarbeid mellom fastleger og et tverrfaglig helseteam gir et bedre helsetilbud enn dagens praksis, og om pasientene da blir mer fornøyd med tilbudet.

Hva innebærer studien for deg?
Deltakelse i studien innebærer at du fyller ut et kort spørreskjema om hvor fornøyd du er med helsetilbudet, og om din generelle og psykiske helsetilstand. Vi vil gjerne sende deg et lignende spørreskjema også om 3 og 9 måneder for å se hvordan din situasjon er da. Vi ber deg også om samtykke til å få opplysninger fra eventuell kontakt med Akershus universitetssykehus og fra noen offentlige registre (NAV, HELFO, Reseptregisteret) for de neste 9 månedene og det siste året.

Mulige fordeler og ulemper
Du vil kunne få et bedre helsetilbud. Du forplikter deg til å svare på et kort spørreskjema nå og om 3 og 9 måneder.

Hva skjer med informasjonen om deg?
Du er en av flere hundre som deltar i studien. Opplysningene om deg vil bli avidentifisert, og de skal bare brukes av forskerne i studien. Alle navn slettes etter at vi har mottatt spørreskjemaene om 9 måneder. Du vil ikke kunne gjenkjennes i resultatene som publiseres fra studien. Du har rett til å få se hvilke opplysninger som er registrert om deg, og du har rett til å få korrigert eventuelle feil i opplysningene. Dersom du trekker deg fra studien, kan du kreve å få slettet opplysningene om deg dersom de ikke er tatt i bruk i analyser.

Frivillig deltakelse
Deltakelsen i undersøkelsen er frivillig. Det vil ikke ha noen innvirkning på helsetilbudet ditt dersom du ikke ønsker å delta. Du kan når som helst trekke deg fra studien, og du trenger ikke å oppgi noen grunn for det.

Akershus universitetssykehus er ansvarlig for studien i samarbeid med Universitetet i Oslo og andre kompetansesentre og brukerorganisasjoner. Dersom du ønsker å motta informasjon om resultatene fra studien, kan du sende beskjed med din adresse til prosjektleder.

Prosjektleder for studien er professor Torleif Ruud, torleif.ruud@ahus.no, tlf 975 46 760.
Adresse: FOU-avdeling psykisk helsevern, Akershus universitetssykehus, 1478 Lørenskog

Tusen takk for hjelpen! Med vennlig hilsen, Torleif Ruud (prosjektleder)

Samtykke

Jeg er villig til å delta at i studien om Samarbeid mellom fastleger og andre helsetjenester.

____
(Sted og dato)

____
(Underskrift)

____
(Navn med store bokstaver)

____
(Adresse)

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___
(Fødselsnummer – 11 siffer)

Skriv her dersom du helst vil motta elektronisk spørreskjema om 3 og 9 måneder:

E-postadresse: ____

Mobiltelefon: __________________________

Ahus FOU-avd PHV

Pasient ☐

Dato ☐

Spørreskjema til pasienter hos fastlegen 2015

	I løpet av den siste uken . . . *(Sett ett kryss på hver linje)*	Aldri	Sjelden	Av og til	Ofte	Nesten hele tiden
1	Har jeg følt meg anspent, engstelig eller nervøs	☐	☐	☐	☐	☐
2	Har jeg følt at jeg hadde noen å støtte meg til når jeg trengte det	☐	☐	☐	☐	☐
3	Har jeg følt meg i stand til å takle det når noe har gått galt	☐	☐	☐	☐	☐
4	Har det å snakke med folk vært for mye for meg	☐	☐	☐	☐	☐
5	Har jeg følt redsel eller panikk	☐	☐	☐	☐	☐
6	Har jeg lagt planer for å gjøre slutt på livet mitt	☐	☐	☐	☐	☐
7	Har jeg hatt problemer med å sovne eller har våknet fort igjen	☐	☐	☐	☐	☐
8	Har jeg følt meg fortvilet eller uten håp	☐	☐	☐	☐	☐
9	Har jeg følt meg ulykkelig	☐	☐	☐	☐	☐
10	Har uønskede bilder eller minner plaget meg	☐	☐	☐	☐	☐

	Mine helseproblemer går ut over det jeg skal gjøre når det gjelder . . . *(Sett ett kryss på hver linje)*	Ikke i det hele tatt	Litt	En del	Mye	Svært mye
11	Arbeid eller utdanning	☐	☐	☐	☐	☐
12	Matlaging, husarbeid, annet å gjøre i hjemmet	☐	☐	☐	☐	☐
13	Sosiale fritidsaktiviteter sammen med andre	☐	☐	☐	☐	☐
14	Private fritidsaktiviteter som jeg gjør alene	☐	☐	☐	☐	☐
15	Kontakt og forhold til familie og andre	☐	☐	☐	☐	☐

	Hvor fornøyd er du med fastlegen? *Sett ett kryss på hver linje*	Svært misfornøyd	Misfornøyd	Både/og	Fornøyd	Svært fornøyd
16	Hvor raskt du får hjelp	☐	☐	☐	☐	☐
17	Hvordan du blir møtt og respektert	☐	☐	☐	☐	☐
18	Om du får den hjelpen du trenger	☐	☐	☐	☐	☐

	Hvor fornøyd er du med psykisk helsevern ved Ahus, om du har hatt kontakt siste 12 måneder? (DPS, BUP, andre) *Sett ett kryss på hver linje*	Har ikke hatt slik kontakt	Svært misfornøyd	Misfornøyd	Både/og	Fornøyd	Svært fornøyd
19	Hvor raskt du får hjelp	☐	☐	☐	☐	☐	☐
20	Hvordan du blir møtt og respektert	☐	☐	☐	☐	☐	☐
21	Om du får den hjelpen du trenger	☐	☐	☐	☐	☐	☐

	Hvor fornøyd er du med ditt samlede helsetilbud? *Sett ett kryss på hver linje*	Svært misfornøyd	Misfornøyd	Både/og	Fornøyd	Svært fornøyd
22	Hvordan helsetjenestene samarbeider	☐	☐	☐	☐	☐
23	Om helsetjenestene forstår din situasjon	☐	☐	☐	☐	☐
24	Hvor nyttig den samlede hjelpen er for deg	☐	☐	☐	☐	☐

25	Alt i alt, hvor fornøyd er du med livet ditt slik det er nå?	☐	☐	☐	☐	☐

Vennligst kontroller at du har svart på alle spørsmålene. **Lever skjemaet i vedlagte konvolutt.** **Tusen takk!**

You may contribute by filling in a short questionnaire regarding your health and your present health care

Multidisciplinary health teams may together with the GP (fastlege) give an extended health care

- Such health teams will be tried in Groruddalen
- You may contribute in a study on the health care

You take part in the study by doing this:

- Give your written consent to your GP (fastlege) or secretary
- Fill in the questionnaire, put it in an envelope in the available box

- You may keep the pages with information on the study
- You will receive a similar short questionnaire in 3 and 9 months

Akershus universitetssykehus

UNIVERSITETET I OSLO

Request to participate in the research project: Cooperation between GPs and other health services

Background and purpose
This is a question for you to participate in a research study carried out in Groruddalen in 2015. We will study the cooperation between GPs (fastleger) and other health services, and particularly how mental health problems possibly in combination with other health problems are taken care of. In a later part of the project we will study whether close collaboration between GPs (fastleger) and a multidisciplinary health team provides a better health care than current practice, and whether the patients then will be more satisfied with the health care.

What does the study involve for you?
Participation in the study involves filling in a short questionnaire about your satisfaction you're your health care, and about your general and mental health. We will like to send you a similar questionnaire 3 and 9 months from now to see how your situation is then. We also ask you for consent to get information on any contact with Akershus University Hospital and from some public registers (NAV, HELFO, Reseptregisteret) for the next nine months and the past year.

Possible advantages and disadvantages
You may get better health care. You agree to answer a short questionnaire now and 3 and 9 months from now.

What happens to the information about you?
You are one of several hundreds who participate in the study. The information about you will be de-identified and they will only be used by researchers in the study. All names are deleted after we have received questionnaires 9 months from now. You will not be recognized in the results published from the study. You have the right to see what information is collected about you, and you have the right to correct any errors in the information. If you withdraw from the study, you can claim to have the information about you deleted, unless it is already used in data analyses.

Voluntary participation
Participation in the survey is voluntary. It will have no impact on your health care if you do not want to participate. You may at any time withdraw from the study, and you do not have to give any reason for it.

Akershus University Hospital is responsible for the study in collaboration with the University of Oslo, other centers of expertise and user organizations. If you wish to receive information on the results of the study, please send a message with your address to the project manager.

Project manager for the study is Professor Torleif Ruud, torleif.ruud@ahus.no , tel 975 46760.
Address: Research Department Mental Health, Akershus University Hospital, 1478 Lørenskog

Thanks you very much for your help!   Sincerely, Torleif Ruud (project manager)

Consent

I am willing to participate in the study Cooperation between GPs and other health services.

____
(Place and date)

____
(Signature)

____
(Name in CAPTIAL LETTERS)

____
(Address)

___ ___ ___ ___ ___ ___   ___ ___ ___ ___ ___
(National identity number)
(Date, month and year of birth (6 digits) and personal number(5 digits))

Write here if you prefer to receive the short questionnaire in 3 and 9 months as an electronic questionnaires for computers, tablets or smart mobile phones:

E-mail address: ____

Mobile Phone: __________________________

Ahus FOU-avd PHV

Patient

Date

Questionnaire to GP patients 2015

	Over the last week . . . *(Mark one box on each line)*	Not at all	Only occasionally	Some-times	Often	Most of the time
1	I have felt tense, anxious or nervous	☐	☐	☐	☐	☐
2	I have felt I have someone to turn to for support when needed	☐	☐	☐	☐	☐
3	I have felt able to cope when things go wrong	☐	☐	☐	☐	☐
4	Talking to people has felt too much for me	☐	☐	☐	☐	☐
5	I have felt panic or terror	☐	☐	☐	☐	☐
6	I made plans to end my life	☐	☐	☐	☐	☐
7	I have had difficulty getting to sleep or staying asleep	☐	☐	☐	☐	☐
8	I have felt despairing or hopeless	☐	☐	☐	☐	☐
9	I have felt despairing or hopeless	☐	☐	☐	☐	☐
10	Unwanted images or memories have been distressing me	☐	☐	☐	☐	☐

	My health problems affect my daily activities regarding . . . *Mark one box on each line*	Not at all	Slightly	Definitely	Markedly	Very severely
11	Work or education	☐	☐	☐	☐	☐
12	Cooking, housekeeping, other household tasks	☐	☐	☐	☐	☐
13	Social or leisure activities together with others	☐	☐	☐	☐	☐
14	Private leisure activities alone / by myself	☐	☐	☐	☐	☐
15	Contact and relationships with family and others	☐	☐	☐	☐	☐

	How satisfied are you with your GP (fastlege)? *Mark one box on each line*	Very dissatisfied	Dis-satisfied	Both/and	Satisfied	Very satisfied
16	How quickly you get help	☐	☐	☐	☐	☐
17	How you are met and respected	☐	☐	☐	☐	☐
18	If you get the help you need	☐	☐	☐	☐	☐

	How satisfied are you with Ahus mental health services (DPS, BUP, others), if you such had contact last 12 months? *Mark one box on each line*	No such contact	Very dissatisfied	Dis-satisfied	Both/and	Satisfied	Very satisfied
19	How quickly you get help	☐	☐	☐	☐	☐	☐
20	How you are met and respected	☐	☐	☐	☐	☐	☐
21	If you get the help you need	☐	☐	☐	☐	☐	☐

	How satisfied are you with your total health care, all in all? *Mark one box on each line*	Very dissatisfied	Dis-satisfied	Both/and	Satisfied	Very satisfied
22	How your health services collaborate (work together)	☐	☐	☐	☐	☐
23	If the health services understand your situation	☐	☐	☐	☐	☐
24	How useful your total health services are for you	☐	☐	☐	☐	☐

25	All in all, how satisfied are you with your life as it is now?	☐	☐	☐	☐	☐

Please check that you have answered all questions. Put the form in an envelope and in the box. Thank you very much!

Prosjektsøknad Skjema for søknad om godkjenning av forskningsprosjekt i de regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK)

Dokument-id: 459270 Dokument mottatt 04.03.2014

Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personer med psykiske og andre sykdommer? Cluster randomisert studie

1. Generelle opplysninger

a. Prosjekttittel

Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personer med psykiske og andre sykdommer? Cluster randomisert studie

Is shared primary and mental healthcare better than current practice for people with mental and comorbid illnesses? Cluster randomized trial

b. Prosjektleder

Navn:	Torleif Ruud
Akademisk grad:	Dr.med.
Klinisk kompetanse:	Spesialist i psykiatri
Stilling:	Avdelingssjef/professor
Hovedarbeidssted:	Akershus universitetssykehus
Arbeidsadresse:	Avdeling forskning og utvikling Divisjon psykisk helsevern
Postnummer:	1478
Sted:	Lørenskog
Telefon:	67968773
Mobiltelefon:	97546760
E-post adresse:	torleif.ruud@ahus.no

c. Forskningsansvarlig

1. Forskningsansvarlig

Institusjon:	Akershus universitetssykehus
Kontaktperson:	Stein Vaaler
Stilling:	Adm direktør

Telefon: 02900
Mobiltelefon: 99156690
E-post adresse: stein.vaaler@ahus.no

d. Andre prosjektopplysninger

Initiativtaker til prosjektet er prosjektleder eller forskningsansvarlig (bidragsforskning)

e. Prosjektmedarbeidere

1. Prosjektmedarbeider

Navn: Ajmal Hussain
Stilling: Overlege/forsker
Institusjon: Akershus universitetssykehus
Akademisk rolle: PhD
Prosjektrolle: Prosjektmedarbeider

2. Prosjektmedarbeider

Navn: Jorun Rugkåsa
Stilling: Seniorforsker
Institusjon: Akershus universitetssykehus
Akademisk rolle: PhD
Prosjektrolle: Prosjektmedarbeider

3. Prosjektmedarbeider

Navn: Nick Kates
Stilling: Professor
Institusjon: McMaster University, Canada
Akademisk rolle: PhD
Prosjektrolle: Prosjektmedarbeider

4. Prosjektmedarbeider

Navn: Svein Gjelstad
Stilling: Fastlege, forsker
Institusjon: Universitetet i Oslo
Akademisk rolle: PhD
Prosjektrolle: Prosjektmedarbeider

5. Prosjektmedarbeider

Navn: Hilde Lurås

Stilling: Forskningssjef

Institusjon: Akershus universitetssykehus

Akademisk rolle: PhD

Prosjektrolle: Prosjektmedarbeider

6. Prosjektmedarbeider

Navn: Anne Signe Landheim

Stilling: Forskningsleder

Institusjon: Kompetansetjenester for ROP lidelser

Akademisk rolle: PhD

Prosjektrolle: Prosjektmedarbeider

7. Prosjektmedarbeider

Navn: Dagfinn Bjørgen

Stilling: FOU-leder

Institusjon: Erfaringskompetanse

Akademisk rolle: Erfaringskompetanse

Prosjektrolle: Prosjektmedarbeider

8. Prosjektmedarbeider

Navn: Ole Rikard Haavet

Stilling: Fastlege, førsteamanuensis

Institusjon: Universitetet i Oslo

Akademisk rolle: PhD

Prosjektrolle: Prosjektmedarbeider

9. Prosjektmedarbeider

Navn: Mette Brekke

Stilling: Fastlege, professor

Institusjon: Universitetet i Oslo

Akademisk rolle: PhD

Prosjektrolle: Prosjektmedarbeider

10. Prosjektmedarbeider

Navn: Inger Cathrine Kann

Stilling: Seniorforsker

Institusjon: Akershus universitetssykehus

Akademisk rolle: PhD

Prosjektrolle: Prosjektmedarbeider

11. Prosjektmedarbeider

Navn:	Inger Cathrine Kann
Stilling:	Seniorforsker
Institusjon:	Akershus universitetssykehus
Akademisk rolle:	PhD
Prosjektrolle:	Prosjektmedarbeider

2. Prosjektopplysninger

a. Formål

Prosjektleders prosjektbeskrivelse

Prosjektet vil undersøke effekten av en norsk tilpasning av en kanadisk modell med et tverrfaglig helseteam med fagpersoner fra primærhelsetjenesten og psykisk helsevern som samlokaliseres og samarbeider tett med fastleger. Vi vil kombinere data fra pasienter om deres psykiske helse og tilfredshet med helsetjenesten, og registerdata om pasienter og bruk av tjenester fra fastleger, psykisk helsevern, kommunenes helsetjeneste og NAV. Seks legesentre med 24 fastleger fra tre bydeler i Groruddalen rekrutteres til prosjektet. Første del er en studie av dagens praksis. Pasientforløp undersøkes ved kombinasjon av data fra de nevnte helsetjenestene. I andre del brukes data fra første del til å identifisere behov for bedre samhandling, og å utforme og implementere en norsk modell med felles helseteam. Tredje del av prosjektet er en cluster randomisert studie for å se om modellen med felles helseteam (ved tre legesentre) gir mer effektivt helsetilbud enn dagens praksis.

b. Forskningsdata

Registerdata

Nye helseopplysninger

Psykiske helseproblemer, bruk av rusmidler, kjønn, alder, livssituasjon. tilfredshet med helsetjenester

c. Forskningsmetode

Statistiske (kvantitative) analysemetoder

Spørreskjema

Begrunnelse for valg av data og metode

Vi ønsker ønsker informasjon direkte fra pasienten om deres helsetilstand og deres tilfredshet med helsetjenestene.

d. Utvalg

Pasienter/klienter

Pasienter som oppsøker fastleger.

Studien gjelder i hvilken grad pasienters psykiske problemer oppdages av fastlegen, hvordan deres helsetilbud blir i primærhelsetjenesten og psykisk helsevern under ulike forhold, og hvordan de er tilfreds med den tjenesten de mottar.

e. Antall forskningsdeltakere

Antall forskningsdeltakere i Norge 1350

Se prosjektbeskrivelsen.

Styrkeberegning

Se prosjektbeskrivelsen.

Særskilte prosjektopplysninger

Registerdata

Regionalt eller lokalt helseregister

NAV, HELFO

Se detaljert oversikt i eget vedlegg.

Pasientjournal

Pasientenes journal hos fastlegen
Pasientenes journal ved Akershus universitetssykehus, Divisjon psykisk helsevern

Se eget vedlegg med detaljert oversikt.

Kobling mellom registre

Se redegjørelse i vedlegget om registerdata og koblinger.

3. Informasjon, samtykke og personvern

Samtykke innhentes for alle data

Spesifikt informert aktivt skriftlig samtykke

Beskrivelse av rekrutteringsprosedyre

Ber pasientene som fyller ut spørreskjema om samtykke til å koble deres opplysninger til data fra pasientjournaler og registerdata.

Det søkes om godkjenning for ikke å innhente samtykke for utvalgte data

Ber om godkjenning til å koble registerdata og få anonymiserte filer for analyse. Se detaljert redegjørelse i vedlegg om dette.

Begrunnelse for ikke å innhente samtykke:

Anonymiserte data

Det er ønskelig å undersøke pasientforløpt for en 12 måneders cohort av pasienter hos de 24 fastlegene i prosjektet, og det er vanskelig å innhente samtykke fra alle disse. Se forøvrig prosjektbeskrivelse og eget vedlegg om bruk av dataregistre.

Det søkes om dispensasjon fra taushetsplikt

Se forrige punkt.

Vi kjenner ikke navn på de det gjelder.

Opplysningene blir anonymisert eller avidentifisert før analyse

4. Forskningsetiske utfordringer ved prosjektet

a. Fordeler

Den enkelte prosjektdeltaker

Den enkelte pasient i første delstudie (WP1) om nåværende praksis vil ikke få noe endret helsetilbud på grunn av studien. En del pasienter i siste delstudie (WP3) om utprøving av et felles helseteam forventes å kunne gi forbedret helsetilbud til en del pasienter.

Grupper av personer

Framtidige pasienter som får tilbud om hjelp fra felles helseteam som er den modellen for tett samhandling som prosjektet vil prøve ut, samt fremtidige pasienter hos fastleger som får økt bevissthet og økt kompetanse på å identifisere psykiske problemer hos pasienter.

Bedre identifisering, behandling og oppfølging av psykiske problemer.

Samfunnet

Utprøving og dokumentasjon av en samhandlingsmodell som er i samsvar med intensjonene i Samhandlingsreformen, og har som hensikt å gi hjelp til flere, identifisere og komme til med behandling tidligere i utvikling av psykiske problemer, og øke effektivitet og ressursutnyttelse i behandling av de mest utbredte psykiske problemer.

Vitenskapen

Ny kunnskap om nytten av en systematisk modell for tett samhandling mellom primærhelsetjenesten og psykisk helsevern, og kunnskap om hva som fremmer og hemmer implementeringen av denne samhandlingsmodellen.

b. Ulemper

Den enkelte prosjektdeltaker

Bruk av tid og eventuelt ubehag ved å fylle ut et spørreskjema på en side med blant annet 10 spørsmål om psykiske problemer, som fylles ut ved besøk hos fastlegen og 3 og 9 måneder seinere.

Grupper av personer

Ser ingen grupper som vil belastes utover de pasientene som velger å samtykke i å fylle ut spørreskjema.

Ingen

Samfunn og miljø

Ser ingen ulemper for samfunn eller miljø.

c. Tiltak

Ingen.

d. Forsvarlighet

Ut fra at belastningen ved å fylle ut det korte spørreskjemaet anses som svært begrenset, og nytten av prosjektet kan bli stor for store grupper av pasienter, anses det som faglig og etisk forsvarlig å gjennomføre prosjektet.

5. Sikkerhet, interesser og publisering

a. Personidentifiserbare opplysninger

Opplysninger som registreres i prosjektet er direkte personidentifserbare - 11-sifret fødselsnummer

b. Internkontroll og sikkerhet

Personidentifiserbare opplysninger oppbevares:

Innelåst

Midlertidig oppbevaring av identifiserbare utfylte spørreskjema og datafiler med identifikasjon før kobling og anonymisering, vil skje ved nedlåsing i stålskap.

Anonymiserte datafiler etter kobling vil bli oppbevart på dedikert forskningsserver ved Akershus universitetssykehus uten tilkobling til internett.

På institusjonens server

c. Forsikringsdekning for deltakere

Pasientskadeerstatningsloven

Forsikring anses unødvendig

Prosjektet innebærer ikke gjennomføring av spesifikke intervensjoner, men en utprøving og testing av nytten av å organisere en tettere samhandling mellom eksisterende helsetjenester om pasienter med psykiske problemer.

d. Vurdering av andre instanser

Internt personvernombud

Dataleverandør

Fastlegene som deltar i prosjektet og gir tilgang til sine pasientdata.
Akershus universitetssykehus som deltar og gir tilgang til sine pasientdata.
NAV som dataleverandør.

e. Interesser

Finansieringskilder

Prosjektet har mottatt 1,5 mill kroner i oppstartingsmidler for forskningen fra Helse SørØst RHF. De ulike involverte prosjektmedarbeidere bruker egen tid som en del av sitt ordinære arbeid. Prosjektet har sendt søknad til Norges forskningsråd (programmet HELSEOMSORG) om midler til to stipendiater (en for WP1 og en for WP3) og noe driftsmidler. Det vil bli sendt søknad til Akershus universitetssykehus om noe driftsmidler.

Godtgjøring til institusjon

Ingen.

Honorar prosjektleder/-medarbeidere

Ingen.

Kompensasjon for forskningsdeltakere

Flakslodd?

Eventuelle interessekonflikter for prosjektleder/-medarbeidere

Ingen.

f. Publisering

Det er ikke restriksjoner med hensyn til offentliggjøring og publisering av resultantene fra prosjektet

Resultatene publiseres som vitenskapelige artikler i norske og internasjonale tidsskrifter, og presenteres i konferanser, kongresser og seminarer for fagfolk og for allmennheten. Fastleger og andre tjenester som deltar vil få tilbakemelding i form av profiler for sin praksis og kan se den i forhold til andre tilsvarende tjenester og pasientenes samlede bruk av helsetjenester. Resultatene vil også bli formidlet til ledere innen helsetjenestene og til helsemyndighetene, og de vil bli gjort kjent på hjemmesider for tjenestene og for brukerorganisasjoner. Dersom modellen med felles helseteam viser seg å være vellykket, vil en også formidle erfaringer til andre steder som ønsker å ta modellen i bruk.

h. Tidsramme

Prosjektstart 01.04.2014

Prosjektslutt 30.06.2018

Etter prosjektslutt skal datamaterialet anonymiseres

Anonymiserte datafiler vil bli oppbevart med tanke på videre publisering og eventuell sammenligning med framtidige materialer.

6. Vedlegg

#	Type	Filnavn	Lagt inn dato
1.	Spørreskjema	Shared care spørreskjema Utkast 2014 0304.pdf	04.03.14
2.	Øvrige vedlegg	Shared care Variabler 2014 0304.pdf	04.03.14
3.	Forespørsel om deltakelse	Shared care Samtykkeskjema 2014 0304.pdf	04.03.14
4.	CV for prosjektleder	CV and publications Ruud.pdf	02.03.14
5.	Forskningsprotokoll	Project description Shared care ES524452.pdf	02.03.14

7. Ansvarserklæring

Jeg erklærer at prosjektet vil bli gjennomført i henhold til gjeldende lover, forskrifter og retningslinjer

Jeg erklærer at prosjektet vil bli gjennomført i samsvar med opplysninger gitt i denne søknaden

Jeg erklærer at prosjektet vil bli gjennomført i samsvar med eventuelle vilkår for godkjenning gitt av REK eller andre instanser

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Anette Solli Karlsen	22845522	07.04.2014	2014/435/REK sør-øst A
			Deres dato:	**Deres referanse:**
			04.03.2014	

Vår referanse må oppgis ved alle henvendelser

Torleif Ruud
Avdeling forskning og utvikling, Divisjon psykisk helsevern, Akershus universitetssykehus

2014/435 Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personer med psykiske og andre sykdommer? Cluster randomisert studie

Forskningsansvarlig: Akershus universitetssykehus
Prosjektleder: Torleif Ruud

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtet 27.03.2014. Vurderingen er gjort med hjemmel i helseforskningsloven § 10, jf. forskningsetikklovens § 4.

Prosjektbeskrivelse

Formålet med prosjektet er å undersøke hvorvidt en norsk tilpasning av en kanadisk modell med tverrfaglig helseteam kan gi et mer effektivt helsetilbud for personer med psykiske og andre sykdommer. Teamene skal bestå av fagpersoner fra primærhelsetjenesten og psykisk helsevern som samlokaliseres og samarbeider tett med fastleger.
Studien er delt i tre arbeidspakker, WP1-WP3.
I WP1 skal nåværende praksis kartlegges ved å undersøke pasientforløp i en klinisk kohort som beskrevet nedenfor. I WP2 skal det brukes data fra WP1 til å identifisere behov for bedre samhandling og å utforme og implementere en norsk modell med felles helseteam. WP3 er en cluster randomisert studie der man skal undersøke om modellen med felles helseteam gir et mer effektivt helsetilbud enn dagens praksis.
Seks legesentre med 24 fastleger fra tre bydeler i Groruddalen er planlagt rekruttert til prosjektet.
Deltakerne skal deles i to kohorter; omtalt som klinisk kohort og registerkohort.
Det totale antall deltakere i den kliniske kohorten er angitt til omlag 1350 pasienter.
Deltakere i den kliniske kohorten skal rekrutteres forløpende over 4 uker fra seks ulike legesentre. For disse skal det gjøres en samtykkebasert innhenting av definerte opplysninger fra fastlegejournal, NAV/HELFO samt Akershus Universitetssykehus prospektivt 9 måneder etter inklusjon. Disse skal samtidig utfylle spørreskjemaer om blant annet psykisk helse, alkohol/rusmidler samt tilfredshet med de tjenester de har mottatt. Skjemaene skal utfylles 3 ganger i samme tidsrom. Deltakerne honoreres med flaxlodd.
Som deltakere i registerkohorten søkes det om å inkludere alle pasienter som har vært til konsultasjon hos de 24 deltakende fastleger de siste 12 måneder. Det søkes om dispensasjon til å innhente opplysninger uten pasientens samtykke fra samme tidsrom fra fastlegejournal, NAV/HELFO og Akershus Universitetssykehus.
Av søknadsskjemaet fremkommer det at man i prosjektet ønsker å koble mot data i reseptregisteret. Prosjektleder har opplyst under saksforberedelsene at denne koblingen ikke er aktuell grunnet registerets pseudonymitet.

Vurdering

Prosjektet kan potensielt bidra til å innhente ny kunnskap om hvorvidt samhandling mellom primærhelsetjeneste og psykisk helsevern kan bidra til et forbedret behandlingstilbud for denne gruppe pasienter.

Det er imidlertid utfordrende å skille mellom hva som er planlagt inkludert i de ulike arbeidspakkene fra søknad og protokoll.

Komiteen forstår prosjektet som en registerstudie uten planlagte intervensjoner. Imidlertid omfatter prosjektet en rekke registerkoblinger som tilsier at prosjektet faller innenfor helseforskningslovens virkeområde og dermed er fremleggingspliktig for REK.

For den delen av studien som omtales som registerkohort planlegges det å innhente opplysninger fra journal og registre uten deltakernes samtykke. REK kan gi adgang til bruk av helseopplysninger innsamlet i helsetjenesten til bruk i forskning uten hinder av taushetsplikt, jf. helseforskningsloven § 35. Dette kan bare skje dersom slik forskning er av vesentlig interesse for samfunnet og hensynet til deltakernes velferd og integritet er ivaretatt og REK kan stille vilkår for bruk av opplysningene. Komiteen stiller spørsmål ved at man for registerkohorten skal hente opplysninger fra fastlegens journal om alle pasienter som har vært til konsultasjon siste 12 måneder. Dette fremstår for komiteen som særs inngripende ovenfor de aktuelle deltakerne. Etter komiteens syn er det ikke gitt 1) tilstrekkelig opplysninger om hensikten med og betydningen av registerkohorten i prosjektet, 2) en utfyllende begrunnelse for innhenting av de angitte opplysningene for alle pasienter som har vært til konsultasjon hos de aktuelle fastlegene innenfor gitt tidsrom og 3) tilstrekkelig informasjon om hvordan de innhentede opplysningene skal bindes opp mot studiens forskningsspørsmål eller endepunkt. På dette grunnlaget kan ikke komiteen ta stilling til fritak for taushetsplikt for registerkohorten.

Det er ikke gitt noen strategi for hvordan legesentre eller fastleger skal rekrutteres til prosjektet.

Det er ikke redegjort for hvilke rutiner som skal følges når journalopplysninger skal hentes fra fastlege eller Ahus for registerkohorten. Variabellisten som er vedlagt henviser til hvilke journalopplysninger og registerdata som skal hentes for den kliniske kohorten. Slik komiteen leser søknad og protokoll kommer det ikke tydelig frem hvilke opplysninger eller variable som er planlagt innhentet for registerkohorten.

Det fremkommer ikke hvordan clusterne skal randomiseres i WP3. Her er det videre ikke forståelig hvorvidt det er lege eller pasient som er definert som «bruker».

Komiteen ber om tilbakemelding på følgende merknader før det fattes et endelig vedtak:

1. På generelt grunnlag bes det om en redegjørelse for hvordan de ulike opplysningene som innhentes i prosjektet skal knyttes opp mot studiens forskningsspørsmål innenfor de ulike arbeidspakkene.
2. Det må redegjøres for hvordan legesentre og fastleger er tenkt rekruttert til studien.
3. Det bes om en tilbakemelding på hvilke rutiner som skal følges når journalopplysninger skal innhentes fra fastleger og sykehus.
4. Spørreskjemaene CORE-10, CAGE-4 og CSQ-8 må ettersendes i norsk oversettelse. I «Shared care» skjemaet må utrykket ACT forklares.
5. Det bes om at det utarbeidede informasjonsskrivet revideres slik at studiens formål og metoder fremkommer på en tydeligere måte.

For den delen av prosjektet der man planlegger å innhente data fra journal og registre uten samtykke, den omtalte registerkohorten, bes det om en redegjørelse på følgende:

1. Hva den primære hensikten med og betydningen av registerkohorten er i prosjektet.
2. Det bes om en redegjørelse for hvilke opplysninger og variable som skal innhentes for disse pasientene- fra journal, sykehus og registre.
3. Det bes om en utfyllende begrunnelse for innhenting av de angitte opplysningene for alle pasienter som har vært til konsultasjon hos de aktuelle fastlegene siste 12 måneder.
4. Det bes om en begrunnelse for at man for registerkohorten skal innvilge dispensasjon fra taushetsplikt etter helseforskningsloven § 35.

For WP3 bes det om en redegjørelse for:

1. Hvordan clusterne skal randomiseres.
2. Hvorvidt det er lege eller pasient som er definert som «bruker».
3. Med hvilke variable man ønsker å besvare de angitte forskningsspørsmål (jf. «Research questions in WP3», s. 2 i vedlegget «Oversikt over data som skal samles inn og kobles»).

Vedtak
Vedtak i saken utsettes. Det bes om tilbakemelding om de merknader som er anført før endelig vedtak fattes. Komiteen tar stilling til godkjenning av prosjektet i møte etter mottatt svar.

Vennligst benytt skjema for tilbakemelding som sendes inn via saksportalen til REK http://helseforskning.etikkom.no. Tilbakemeldingen må være oss i hende innen seks måneder.

Med vennlig hilsen

Knut Engedal
Professor dr. med.
Leder

Anette Solli Karlsen
Komitesekretær

Kopi til: *stein.vaaler@ahus.no*; *postmottak@ahus.no*

Svarbrev til REK ang 2014/435/REK sør-øst

Vi takker komiteen for brev av 07.04.14 med referanse 2014/435/REK sør-øst, og i avsnittene nedenfor redegjør vi for de spørsmål som komiteen ønsker belyst med ytterligere opplysninger.

Vi ber om at søknaden ferdigbehandles i møte 8.mai ut fra svarene i dette brevet og følgende vedlegg: Revidert samtykke av 2014 0429, og norsk versjon av instrumenter til spørreskjema.

Siden komiteens spørsmål i hvert av de tre områdene var nummerert fra 1 og oppover, har vi for oversiktens skyld kalt de tre områdene A, B og C og nummerert spørsmålene A1, A2… B1, B2… osv. Spørsmålene fra REK er skrevet i kursiv, og våre svar med vanlige skrifttyper.

A.Komiteen ber om tilbakemelding på følgende merknader før det fattes et endelig vedtak:

A1.På generelt grunnlag bes det om en redegjørelse for hvordan de ulike opplysningene som innhentes i prosjektet skal knyttes opp mot studiens forskningsspørsmål innenfor de ulike arbeidspakkene.
Vi har laget en tabell over dette for WP1 og en tabell for WP3. Siden dette spørsmålet for WP3 er sammenfallende med spørsmål C3, har vi plassert begge disse tabellene under svaret på spørsmål C3 bakerst i dette dokumentet.

A2.Det må redegjøres for hvordan legesentre og fastleger er tenkt rekruttert til studien.
Vi velger ut to legesentre med omtrent samme størrelse (4-5 fastleger) i hver bydel. Fastlegene ved hvert legesenter må være villige til å bli randomisert (se svar på spørsmål C2 angående hvordan) samlet til «shared care» eller «ikke shared care» under WP3. Denne randomiseringen må gjøres i mai/juni 2014, siden vi vil invitere 1-2 fastleger fra hver av de tre legesentrene som får «shared care» med på studiereisen til Hamilton i Canada i begynnelsen av september 2014 for at de skal få best mulig bakgrunn til å være med på å utforme den norske varianten av «shared care».

Rekrutteringen av grupper av fastleger til prosjektet vil gjøres i mai 2014 ved at prosjektgruppen tar kontakt med de aktuelle legesentre og avtaler tid for informasjonsmøte hvert sted. Dette gjennomføres av Ole Rikard Haavet (fastlege på deltid, har tidligere vært fastlege/bydelsoverlege i den ene bydelen, førsteamanuensis ved Avdeling for allmennmedisin ved UiO, kjent av mange fastleger), Ajmal Hussain (overlege ved Groruddalen DPS, samarbeider med fastlegene i bydelene, har doktorgrad, skal være psykiater i det planlagte «shared care» opplegget) og Mina Dahli (fastlege, vil være phd-stipendiat i prosjektet og være den som besøker legesentrene under datainnsamlingen og gjennomfører uttrekket av data ved hvert legesenter). Samlet dekker disse tre svært godt samarbeidsflaten mellom prosjektet og fastlegene. Ole Rikard Haavet og Mina Dahli vil kontakte hvert legesenter for å avtale tid for møte.

A3.Det bes om en tilbakemelding på hvilke rutiner som skal følges når journalopplysninger skal innhentes fra fastleger og sykehus.
Rutiner for innhenting av journalopplysninger fra fastleger:
Datauttrekk fra fastlegenes journalsystemer og tilsvarende registre ved den lokale kommunale legevakt og psykiatrisk legevakt, vil bli gjort ved hjelp av programvare utviklet av Svein Gjelstad, som er allmennlege og forsker og medlem av forskergruppen. Han har arbeidet med dette i mange år som fastlege, og har et selskap (Mediata) som har spesialisert seg på slike datauttrekk og gjort det for flere studier, samt for NOKLUS praksisprofil og det norske diabetesregisteret for voksne (www.noklus.no). Mediata lager et spesialtilpasset datautrekksprogram for det elektroniske pasientjournal-systemet som er i bruk på hvert legesenter og på legevakta. Programmet leveres på en USB-minnepinne. Stipendiaten eller en annen i forskergruppen vil gjennomføre selve datauttrekket ved besøk ved hvert legesenter. Programmet installeres på aktuell maskin, og kjøres i

løpet av 1-3 minutter. Resultatene blir lagret i en kryptert fil på den samme minnepinnen. Denne filen blir så levert til koblingsinstansen der de blir dekryptert og koblet med øvrige registerdata.

Rutiner for innhenting av journalopplysninger fra sykehus (Ahus):
Datauttrekk fra det elektroniske datasystemet (DIPS) ved Akershus universitetssykehus gjøres ved IT-ingeniører i Datafangstgruppen ved sykehusets Forskningssenter, som har arbeidet med slike datauttrekk for mange prosjekter og kjenner datasystemet godt. Datafil lagres på sikkert område på forskningsserver ved Akershus universitetssykehus. Datafangstgruppen kan levere datafil med personnummer til NAV for kobling til andre data ved NAV, og slik at verken prosjektleder eller andre i prosjektgruppen får tilgang til datafil med personnummer for registerkohorten.

Ferdig samlet datafil for registerkohorten uten personnumer legges også på sikkert område på forskningsserver ved Akershus universitetssykehus, og bare prosjektleder og noen få forskere får tilgang til denne. De som skal analysere data får tilgang til datafiler med relevante utvalg av data og der datoer er erstattet med andre fremstillinger av omfang og rekkefølge av bruk av ulike tjenester.

Prosjektleder Torleif Ruud kjenner også datasettet godt, da det bygger på det nasjonale datasettet han var med på å revidere i sin tid som forskningssjef for SINTEF Psykisk Helse. Fra sine år som forskningssjef i SINTEF har han også omfattende erfaring med å håndtere og bruke store datasett innen helsetjenesteforskning på psykisk helsevern og delvis primærhelsetjenesten.

A4.Spørreskjemaene CORE-10, CAGE-4 og CSQ-8 må ettersendes i norsk oversettelse. I «Shared care» skjemaet må utrykket ACT forklares.
Norsk versjon av de nevnte instrumentene vedlegges. Uttrykket ACT er fjernet, da det ikke skal være med (var kommet med ved kopiering fra spørreskjemaet som var brukt i annen sammenheng).

A5.Det bes om at det utarbeidede informasjonsskrivet revideres slik at studiens formål og metoder fremkommer på en tydeligere måte.
Revidert informasjonsskriv og samtykke vedlegges. Vi har lagt mye arbeid i å forenkle språket slik at det er blitt tydeligere og lettere å forstå både formålet med studien og metodene som brukes.

B.For den delen av prosjektet der man planlegger å innhente data fra journal og registre uten samtykke, den omtalte registerkohorten, bes det om en redegjørelse på følgende:

B1.Hva den primære hensikten med og betydningen av registerkohorten er i prosjektet.
Registerkohorten er en viktig del av prosjektet av følgende grunner:

- Studien av registerkohorten i WP1 vil i seg selv gi ny kunnskap om pasientfordeling og pasientforløp mellom primærhelsetjenesten og psykisk helsevern ved at vi får koblet data på personnivå fra både fastleger, primærhelsetjenesten, sosialtjenester (NAV) og psykisk helsevern for samme tidsrom. Vi kjenner ingen slik kvantitativ undersøkelse av samlede pasientforløp innen førstelinjetjenesten og psykisk helsevern.
- Denne kunnskapen om mønstre i nåværende praksis er en viktig del av grunnlaget for WP2, der tjenestene sammen skal utforme den lokalt tilpassede modellen for «shared care» som skal prøves ut i WP3. Denne kunnskapen kan gi helsearbeiderne i de ulike tjenestene oversikt over nåværende praksis og bidra til konstruktive forslag om forbedringer.
- Studien av registerkohorten i WP3 i 2016 vil vise om en har oppnådd de ønskelig endringene i tilgang, pasientforløp og pasientfordeling ved etablering av «shared care» i 2015. Vi vil sammenligne «shared care» ved tre legesentre både med vanlig praksis på samme tid ut fra de andre tre legesentrene, men også med tidligere praksis i 2014 ved de tre

legesentrene som deltar i «shared care» (og dermed også kontrollere statistisk for eventuelle systematiske forskjeller i 2014 mellom de to gruppene legesentre).

Analyser av pasientforløp og pasientfordeling innebærer analyser av henvisningsmønstre, ventetid, antall og andel av pasienter som mottar tilbud fra ulike tjenester, varighet og hyppighet av ulike tilbud, og om samtidige helsetilbud på tvers av tjenester og forvaltningsnivå.

For å kunne analysere og sammenligne pasientforløp på denne måten, må vi både ha mange nok pasienter til å få målbar forekomst av ulike mønstre, og vi må følge pasientene over tid for kunne identifisere ulike forløp. Vi har derfor vurdert at det er nødvendig med en registerkohort i både WP1 og WP3, og at det er behov for å inkludere alle pasientene til de ca 24 fastlegene og all bruk av ulike helsetjenester over 12 måneder (se også svar på spørsmål B3).

Den kliniske kohorten vil kunne gi svar på noen spørsmål som registerkohorten ikke kan svare på, fordi vi for den mer avgrensede kliniske kohorten får pasientenes egne utsagn om ulike forhold. Dette gjelder for eksempel andel pasienter med psykiske problemer (målt ved CORE-OM 10) der fastlegene ikke setter noen P-kode fra ICPC-2.

Registerkohorten vil kunne si noe om hvor representativ den kliniske kohorten er, og dermed også noe om generaliserbarheten av funnene basert på den kliniske kohorten.

B2.Det bes om en redegjørelse for hvilke opplysninger og variable som skal innhentes for disse pasientene- fra journal, sykehus og registre.
Vi viser til de tre detaljerte tabellene over dette i vedlegget «Shared care Variabler 2014 0304» i vår søknad av 04.03.2014. Vi viser også til tabellene under spørsmål C3 om bruk av hver variabel for å besvare forskningsspørsmålene.

B3.Det bes om en utfyllende begrunnelse for innhenting av de angitte opplysningene for alle pasienter som har vært til konsultasjon hos de aktuelle fastlegene siste 12 måneder.
Groruddalen DPS får 800 henvisninger fra de 80 fastlegene i bydelene i løpet av et år, altså 10 henvisninger fra hver fastlege, og 240 henvisninger fra 24 fastleger. Vi trenger et materiale fra 12 måneder for å kunne måle forskjell i antall henvisninger mellom nåværende praksis og ved «shared care». Det er også viktig med data for 12 måneder for å kunne analysere pasientforløp og mønstre i behandlingsepisoder, for slike episoder har oftest en varighet på noen uker eller noen måneder.

Et viktig aspekt er også å analysere hvordan pasientgrupper er fordelt mellom fastleger og psykisk helsevern, og om dette endrer seg ved «shared care». Det er vist at fastleger ikke identifiserer alle med psykiske plager, og til dels gir disse andre P-koder. Vi vil se om vi kan finne slike grupper og se om disse i større grad vil fanges opp og få hjelp ved «shared care». Vi trenger da et stort materiale for å kunne måle forskjeller for slike undegrupper. Se også svar på spørsmål B1 ovenfor.

B4.Det bes om en begrunnelse for at man for registerkohorten skal innvilge dispensasjon fra taushetsplikt etter helseforskningsloven § 35.
I følge helseforskningslovens §35 kan REK bestemme at opplysninger innsamlet i helse- og omsorgstjenesten kan gis til bruk i forskning uten hinder av samtykke «dersom slik forskning er av vesentlig interesse for samfunnet og hensynet til deltakernes velferd og integritet er ivaretatt».

Vi mener at registerstudiene i WP1 og WP3 vil bidra til ny kunnskap som er viktig for å kunne gi befolkningen et helsetilbud som er mer i samsvar med befolkningens behov og med intensjonene i Samhandlingsreformen. Vi mener at dette er av vesentlig interesse for befolkningen og for samfunnet, slik det også fremgår av svar på spørsmål B1 ovenfor. Vi mener også at hensynet til deltakernes velferd og integritet vil bli vektlagt og godt ivaretatt i dette prosjektet, og at prosjektgruppen har omfattende kunnskap og erfaring i hvordan dette skal gjøres.

C.For WP3 bes det om en redegjørelse for:

C1.Hvordan clusterne skal randomiseres.
For å kunne gjøre en cluster-randomisert studie ønsker vi å rekruttere fastlegene ved to legesentre i hver av de tre bydelene, slik at vi kan gjøre en stratifisert randomisering til «shared care» med en legegruppe fra hver bydel til henholdsvis med og uten «shared care» i WP3. Det blir dermed tre legesentre (ett i hver bydel) som deltar i «shared care», og tre legesentre (ett i hver bydel) som fortsetter med vanlig praksis. Randomiseringen av de to rekrutterte fastlegegruppene fra hver bydel gjøres ved en elektronisk løsning i et dataprogram for randomisering.

Vi presiserer at det er fastlegene som randomiseres, men vi vil unngå ulike randomisering av fastleger innen samme legegruppe fordi dette vil gi mulighet for overlapping og vanskeliggjøre testing av «shared care».

C2.Hvorvidt det er lege eller pasient som er definert som «bruker».
I alle papirene i prosjektet mener vi pasient med ordet «bruker» og «user», i samsvar med slik «bruker» anvendes i dokumenter fra norske helsemyndigheter og med begrepet «service user».

C3.Med hvilke variable man ønsker å besvare de angitte forskningsspørsmål (jf. «Research questions in WP3», s. 2 i vedlegget «Oversikt over data som skal samles inn og kobles»).

Som nevnt under spørsmål A1 har vi plassert tabeller for både WP1 og WP3 her.

NB: Vi kombinerer resultater fra de ulike kohorter slik at registerkohort viser praksis og forskjeller/endringer i denne, mens klinisk kohort og helsearbeiderkohort viser erfaringer og vurderinger av kvalitet og forskjeller/endringer i kvalitet.

Tabell over forskningsspørsmål i WP1

	Forskningsspørsmål	Kohorter og variabler som skal brukes for å besvare spørsmålet
1	What are the characteristics of patients seen in the current practice (ICPC-2 codes, mental health problems, drug problems, functioning, service utilization, quality of life)?	Registerkohort: Antall og andel pasienter som bruker ulike typer tjenester, sosiodemografiske data, ICPC2-koder, ICD-10 diagnoser, arbeid/sykefravær, ytelser fra NAV/offentlige tjenester. Klinisk kohort: Sosiodemografiske data, ICPC2-koder, spørsmål om psykiske problemer (CORE-10), rusbruk (CAGE), funksjonsnivå, livskvalitet.
2	How satisfied are patients with the services they receive and the collaboration between them?	Klinisk kohort: CSQ8 og andre spørsmål om tilfredshet med helsetjenestene og om samhandlingen mellom disse.
3	What are the patterns of collaborative contacts and activities?	Registerkohort: Henvisninger, svar på henvisninger, samarbeidsmøter (normaltarifftakst), eventuelt prosedyrekoder ved sykehus/poliklinikker. Helsearbeiderkohort: Spørsmål til helsearbeidere i de ulike tjenestene om deres vurdering av nåværende tjenester, kompetanse og samhandling.
4	What do the GPs, primary care and mental health services want and need regarding collaboration and competence?	Helsearbeiderkohort: Spørsmål til helsearbeidere i de ulike tjenestene om deres vurdering av nåværende tjenester, kompetanse og samhandling.

Tabell over forskningsspørsmål i WP3

	Forskningsspørsmål	Kohorter og variabler som skal brukes for å besvare spørsmålet
1	What are the experiences of the users with shared care compared to current practice?	Klinisk kohort: CSQ8 og andre spørsmål om tilfredshet med helstjenestene og om samhandlingen mellom disse. Sammenligning både på tvers av grupper i WP3 og med data fra WP1. Spørsmål om «shared care»
2	What is the impact on services utilization and referral patterns?	Registerkohort: Antall og andel som henvises, fordeling av pasienter på ulike typer helsetjenester, bruk av ulike typer helsetjenester.
3	Is there an increase in availability (more users treated for mental health problems?)	Klinisk kohort: Antall og andel pasienter som bruker ulike typer tjenester (inkludert tilbudene i «shared care»), hva slags behandling de får. Klinisk kohort: Om en større andel av de med psykiske problem (CORE-10) får P-koder fra fastlegen, og om de får tilbud fra «shared care».
4	Successful earlier intervention in the course of illness (prevention, shorter waiting time)?	Registerkohort: Eventuelle endringer i profil på polikliniske behandlinger, innleggelser, ventetid, kortere behandlingstid. Klinisk kohort: Eventuelle endringer i profil på polikliniske behandlinger, innleggelser, ventetid, raskere bedring (CORE-10), større bedring, kortere behandlingstid.
5	Is co-morbidity (somatic, substance abuse) better identified and treated with the Norwegian shared care model than in current practice?	Registerkohort: Større andel pasienter med både P-koder og andre koder, mer samtidig behandling av komorbiditet mer samhandling og koordinering av behandling ut fra data også om «shared care» Klinisk kohort: Større andel pasienter med psykiske problem (CORE-10) får P-koder og samtidig behandling av komorbiditet (hvordan måle?), mer samhandling og koordinering av behandling (hvordan måle?).
6	Are there competences in service providers that promote closer collaboration?	Helsearbeiderkohort: Spørsmål til helsearbeidere i de ulike tjenestene om deres vurdering av nåværende tjenester, kompetanse og samhandling. Data også om «shared care»
7	Are GPs and other services more satisfied with the Norwegian shared care model than with their earlier practice?	Helsearbeiderkohort: Spørsmål til helsearbeidere i de ulike tjenestene om deres vurdering av egen praksis, andre tjenester, og samhandling. Spørsmål også om «shared care»
8	What is the patient course and outcome with the Norwegian shared care model compared to current practice?	Ventetid på adekvat behandling (f.eks. psykiatrisk sykepleier føler seg tettere fulgt opp, fastlegen starter behandling tidligere og ferdigbehandler flere, kommunehelsetjenesten tar over pasienter på et tidligere tidspunkt etc.)
9	What is the impact on the patient experience?	Klinisk kohort: Pasientenes opplevelse av egen helse og bedring av den, og deres erfaringer med helstilbudet (inkluder data om «shared care»).
10	Also increase in collaboration between GPs and primary health care?	Registerkohort: Antall og andel pasienter som bruker ulike typer tjenester, sosiodemografiske data, ICPC2-koder, ICD-10 diagnoser, samarbeidsmøter (normaltarifftakst), eventuelt prosedyrekoder ved sykehus/poliklinikker. Klinisk kohort: CSQ8 og andre spørsmål om tilfredshet med helstjenestene og om samhandlingen mellom disse. Sammenligning både på tvers av grupper i WP3 og med data fra WP1. Helsearbeiderkohort: Spørsmål til helsearbeidere i de ulike tjenestene om deres vurdering av nåværende tjenester, kompetanse og samhandling.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Anette Solli Karlsen	22845522	22.05.2014	2014/435/REK sør-øst A
			Deres dato:	Deres referanse:
			30.04.2014	

Vår referanse må oppgis ved alle henvendelser

Torleif Ruud
Akershus universitetssykehus HF

2014/435 Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personer med psykiske og andre sykdommer? Cluster randomisert studie

Prosjektleder: Torleif Ruud
Forskningsansvarlig: Akershus universitetssykehus HF

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtene 27.03.2014 og 08.05.2014. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikklovens § 4.

Opprinnelig prosjektbeskrivelse

Formålet med prosjektet er å undersøke hvorvidt en norsk tilpasning av en kanadisk modell med tverrfaglig helseteam kan gi et mer effektivt helsetilbud for personer med psykiske og andre sykdommer. Teamene skal bestå av fagpersoner fra primærhelsetjenesten og psykisk helsevern som samlokaliseres og samarbeider tett med fastleger.

Studien er delt i tre arbeidspakker, WP1-WP3. I WP1 skal nåværende praksis kartlegges ved å undersøke pasientforløp i en klinisk kohort som beskrevet nedenfor. I WP2 skal det brukes data fra WP1 til å identifisere behov for bedre samhandling og å utforme og implementere en norsk modell med felles helseteam. WP3 er en cluster randomisert studie der man skal undersøke om modellen med felles helseteam gir et mer effektivt helsetilbud enn dagens praksis.

Seks legesentre med 24 fastleger fra tre bydeler i Groruddalen er planlagt rekruttert til prosjektet.

Deltakerne skal deles i to kohorter; omtalt som klinisk kohort og registerkohort. Det totale antall deltakere i den kliniske kohorten er angitt til omlag 1350 pasienter.

Deltakere i den kliniske kohorten skal rekrutteres forløpende over 4 uker fra seks ulike legesentre. For disse skal det gjøres en samtykkebasert innhenting av definerte opplysninger fra fastlegejournal, NAV/HELFO samt Akershus universitetssykehus HF prospektivt 9 måneder etter inklusjon. Disse skal samtidig utfylle spørreskjemaer om blant annet psykisk helse, alkohol/rusmidler samt tilfredshet med de tjenester de har mottatt. Skjemaene skal utfylles 3 ganger i samme tidsrom. Deltakerne honoreres med Flax-lodd.

Som deltakere i registerkohorten søkes det om å inkludere alle pasienter som har vært til konsultasjon hos de 24 deltakende fastleger de siste 12 måneder. Det søkes om dispensasjon til å innhente opplysninger uten pasientens samtykke fra samme tidsrom fra fastlegejournal, NAV/HELFO og Akershus universitetssykehus

HF.

Av søknadsskjemaet fremkommer det at man i prosjektet ønsker å koble mot data i Reseptregisteret. Prosjektleder har opplyst under saksforberedelsene at denne koblingen ikke er aktuell grunnet registerets pseudonymitet.

Saksbehandling

Søknaden ble behandlet i møte den 27.03.2014, og det ble fattet et utsettende vedtak.

Komiteen ba om tilbakemelding på følgende merknader før det fattes et endelig vedtak:

1. På generelt grunnlag bes det om en redegjørelse for hvordan de ulike opplysningene som innhentes i prosjektet skal knyttes opp mot studiens forskningsspørsmål innenfor de ulike arbeidspakkene.
2. Det må redegjøres for hvordan legesentre og fastleger er tenkt rekruttert til studien.
3. Det bes om en tilbakemelding på hvilke rutiner som skal følges når journalopplysninger skal innhentes fra fastleger og sykehus.
4. Spørreskjemaene CORE-10, CAGE-4 og CSQ-8 må ettersendes i norsk oversettelse. I «Shared care» skjemaet må utrykket ACT forklares.
5. Det bes om at det utarbeidede informasjonsskrivet revideres slik at studiens formål og metoder fremkommer på en tydeligere måte.

For den delen av prosjektet der man planlegger å innhente data fra journal og registre uten samtykke, den omtalte registerkohorten, bes det om en redegjørelse på følgende:

1. Hva den primære hensikten med og betydningen av registerkohorten er i prosjektet.
2. Det bes om en redegjørelse for hvilke opplysninger og variable som skal innhentes for disse pasientene- fra journal, sykehus og registre.
3. Det bes om en utfyllende begrunnelse for innhenting av de angitte opplysningene for alle pasienter som har vært til konsultasjon hos de aktuelle fastlegene siste 12 måneder.
4. Det bes om en begrunnelse for at man for registerkohorten skal innvilge dispensasjon fra taushetsplikt etter helseforskningsloven § 35.

For WP3 bes det om en redegjørelse for:

1. Hvordan clusterne skal randomiseres.
2. Hvorvidt det er lege eller pasient som er definert som «bruker».
3. Med hvilke variable man ønsker å besvare de angitte forskningsspørsmål (jf. «Research questions in WP3», s. 2 i vedlegget «Oversikt over data som skal samles inn og kobles»).

Prosjektleder har sendt tilbakemelding, denne ble mottatt 30.04.2014.

Av tilbakemeldingen fremkommer det at to legesentre med samme størrelse er planlagt inkludert i prosjektet, hver med 4-5 fastleger. Det fremkommer at Mediata vil være ansvarlige for uthenting av journalopplysninger, fra legesentre og legevakt. Uthenting vil skje til en kryptert minnepinne som benyttes for overføring av data til en forskningsfil ved AHus.

Spørreskjemaene CORE-10, CAGE-4 og CSQ-8 er vedlagt i norsk versjon. Informasjonsskriv er revidert i forhold til komiteens merknader.

Som begrunnelse for å innhente data fra alle de aktuelle fastlegenes pasienter med fritak fra å innhente samtykke fra den enkelte pasient med hjemmel i helseforskningslovens § 35 argumenterer prosjektleder med at det vil være viktig å sammenligne antall og type henvendelser fra den enkelte fastlege før og etter implementering av «shared care» modellen. Som et resultat av «shared care» modellen kan man anta at det utvikles et bedre helsetilbud, som på sikt vil være av stor samfunnsmessig betydning i form av bedre utredning og behandling og da spesielt for utsatte pasientgrupper.

Til implementering av «shared care» modellen er det planlagt inkludert seks legesenter i prosjektet, fra tre ulike bydeler. Av disse skal et legesenter i hver bydel randomiseres til «shared care» og da et legesenter i hver bydel som fortsetter vanlig praksis. Det fremkommer at det med bruker her menes pasienten.

Det er gitt en oversikt over hvilke variable som skal knyttes opp mot de enkelte forskningsspørsmål.

Ny vurdering

Komiteen anser prosjektleders tilbakemelding som tilfredsstillende i forhold til å besvare de merknader som er anført om den kliniske kohorten. Komiteen har ingen innvendinger mot at denne delen av prosjektet gjennomføres slik det nå fremkommer av søknad, protokoll og tilbakemelding.

Vedrørende det reviderte informasjonsskrivet er det ikke samsvar mellom formuleringene «Du vil kunne få et bedre helsetilbud» og «Det vil ikke ha noen innvirkning på helsetilbudet ditt dersom du ikke ønsker å delta». Dette må justeres.

Når det gjelder den planlagte registerkohorten, anser komiteen det som inngripende ovenfor den enkelte pasient at deres fastlege skal utlevere opplysninger om sensitive forhold til forskning uten at det foreligger samtykke til dette. REK kan bestemme at helseopplysninger innsamlet i helse- og omsorgstjenesten kan utleveres til bruk i forskning, og at det kan skje uten hinder av taushetsplikt, jf. helseforskningsloven § 35. Dette kan bare skje dersom slik forskning er av vesentlig interesse for samfunnet og hensynet til deltakernes velferd og integritet er ivaretatt. Komiteen anser imidlertid ikke prosjektleders redegjørelse for betydningen av å innhente opplysningene som en tilstrekkelig begrunnelse for å gi fritak for å innhente samtykke til å bruke opplysningene uten at de aktuelle pasientene er gitt en mulighet til å reservere seg mot dette.

Det forutsettes for den planlagte registerkohorten at fastlegen informerer den enkelte pasient om at opplysninger fra journal er planlagt utlevert til forskningsprosjektet, og at den enkelte pasient gis anledning til å reservere seg mot at sine opplysninger utleveres. Det bes dermed om at det utarbeides et skriv med det formål å innhente passivt samtykke for deltakerne i registerkohorten med mulighet for reservasjonsadgang, og at dette innsendes til vårt arkiv.

Vedtak:

Komiteen godkjenner prosjektet i henhold til helseforskningsloven § 9 og § 33 under forutsetning av at ovennevnte vilkår oppfylles.

I tillegg til vilkår som fremgår av dette vedtaket, er godkjenningen gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Det bes om at skriv for passivt samtykke og mulighet for reservasjonsadgang innsendes til arkivet.

Godkjenningen gjelder til 30.06.2018.

Av dokumentasjonshensyn skal opplysningene oppbevares i 5 år etter prosjektslutt. Opplysningene skal oppbevares avidentifisert, dvs. atskilt i en nøkkel- og en datafil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren».

Prosjektet skal sende sluttmelding på eget skjema, jf. helseforskningsloven § 12, senest et halvt år etter prosjektslutt.

Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK, jf. helseforskningsloven § 11.

Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. helseforskningsloven § 10 tredje ledd og forvaltningsloven § 28. En eventuell klage sendes til REK sør-øst A. Klagefristen er tre uker fra mottak av dette brevet, jf. forvaltningsloven § 29.

Med vennlig hilsen

Knut Engedal
Professor dr. med.
Leder

Anette Solli Karlsen
Komitesekretær

Kopi til: Akershus universitetssykehus HF ved øverste administrative ledelse: hilde.luras@ahus.no,;

Klage Skjema for klage på vedtak i de regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK)

Dokument-id: 496497

Tilbakemelding

1. Generelle opplysninger

a. Prosjekt

Tilbakemelding (2014/435)

Prosjektmedarbeider

Ingen prosjektmedarbeidere

b. Prosjektleder:

Navn:	Torleif Ruud
Akademisk grad:	Dr.med.
Klinisk kompetanse:	Spesialist i psykiatri
Stilling:	Avdelingssjef/professor
Arbeidssted:	Akershus universitetssykehus
Arbeidsadresse:	Avdeling forskning og utvikling
Adresse2	Divisjon psykisk helsevern
Postnummer:	1478
Sted:	Lørenskog
Telefon:	67968773
Mobiltelefon:	97546760
E-post adresse:	torleif.ruud@ahus.no

2. Klage

a. Komiteens vedtak

Komiteen godkjenner prosjektet i henhold til helseforskningsloven § 9 og § 33 under forutsetning av at ovennevnte vilkår oppfylles.
I tillegg til vilkår som fremgår av dette vedtaket, er godkjenningen gitt under forutsetning av at

prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.
Det bes om at skriv for passivt samtykke og mulighet for reservasjonsadgang innsendes til arkivet.
Godkjenningen gjelder til 30.06.2018.
Av dokumentasjonshensyn skal opplysningene oppbevares i 5 år etter prosjektslutt.
Opplysningene skal oppbevares avidentifisert, dvs. atskilt i en nøkkel- og en datafil.
Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.
Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren».
Prosjektet skal sende sluttmelding på eget skjema, jf. helseforskningsloven § 12, senest et halvt år etter prosjektslutt.
Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK, jf. helseforskningsloven § 11.
Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. helseforskningsloven § 10 tredje ledd og forvaltningsloven § 28. En eventuell klage sendes til REK sør-øst A. Klagefristen er tre uker fra mottak av dette brevet, jf. forvaltningsloven § 29.

b. Komiteens vurdering og evt vilkår

Ny vurdering
Komiteen anser prosjektleders tilbakemelding som tilfredsstillende i forhold til å besvare de merknader som er anført om den kliniske kohorten. Komiteen har ingen innvendinger mot at denne delen av prosjektet gjennomføres slik det nå fremkommer av søknad, protokoll og tilbakemelding.
Vedrørende det reviderte informasjonsskrivet er det ikke samsvar mellom formuleringene «Du vil kunne få et bedre helsetilbud» og «Det vil ikke ha noen innvirkning på helsetilbudet ditt dersom du ikke ønsker å delta». Dette må justeres.
Når det gjelder den planlagte registerkohorten, anser komiteen det som inngripende ovenfor den enkelte pasient at deres fastlege skal utlevere opplysninger om sensitive forhold til forskning uten at det foreligger samtykke til dette. REK kan bestemme at helseopplysninger innsamlet i helse- og omsorgstjenesten kan utleveres til bruk i forskning, og at det kan skje uten hinder av taushetsplikt, jf. helseforskningsloven § 35. Dette kan bare skje dersom slik forskning er av vesentlig interesse for samfunnet og hensynet til deltakernes velferd og integritet er ivaretatt. Komiteen anser imidlertid ikke prosjektleders redegjørelse for betydningen av å innhente opplysningene som en tilstrekkelig begrunnelse for å gi fritak for å innhente samtykke til å bruke opplysningene uten at de aktuelle pasientene er gitt en mulighet til å reservere seg mot dette.
Det forutsettes for den planlagte registerkohorten at fastlegen informerer den enkelte pasient om at opplysninger fra journal er planlagt utlevert til forskningsprosjektet, og at den enkelte pasient gis anledning til å reservere seg mot at sine opplysninger utleveres. Det bes dermed om at det utarbeides et skriv med det formål å innhente passivt samtykke for deltakerne i registerkohorten med mulighet for reservasjonsadgang, og at dette innsendes til vårt arkiv.

c. Ønsket omgjøring

Vi ønsker omgjøring av vedtaket i de to siste avsnitt ovenfor, der det forutsettes for den planlagte registerkohorten at fastlegen informerer den enkelte pasient om at opplysninger fra journal er planlagt utlevert til forskningsprosjektet, og at den enkelte pasient gis anledning til å reservere seg mot at sine opplysninger utleveres.

Vi mener at prosjektet er av vesentlig interesse for samfunnet, og at REK derfor kan bestemme at opplysninger i fastlegens journal kan utleveres til prosjektet i henhold til helseforskningsloven § 35 uten hinder av taushetsplikt.

Vi merker oss at komiteen anser at prosjektleders redegjørelse for betydningen av å innhente opplysningene for registerkohorten ikke er tilstrekkelig begrunnet for å gi fritak for å innhente samtykke til å bruke opplysningene uten at de aktuelle pasientene er gitt en mulighet til å reservere seg mot dette, og gir derfor nedenfor mer utførlig begrunnelse under tre hovedpunkter: (A) Hvordan prosjektet er av vesentlig interesse for samfunnet. (B) Registerkohortens betydning for dette. (C) Adgang for utlevering av data fra fastlegers journaler på samme måte og med fritak for å innhente samtykke er gitt i et annet prosjekt.

(A) HVORDAN PROSJEKTET ER AV VESENTLIG INTERESSE FOR SAMFUNNET
Family Health Teams som samhandlingsteam med base i primærhelsetjenesten har i Hamilton Canada ført til at mer en ti ganger så mange pasienter får en generell utredning av mental helse, og har opprettholdt denne økte tilgangen over 15 år. Dette er tre ganger så mange henvisninger som de psykiatriske poliklinikkene i byen mottar, og antallet henvisninger til poliklinikkene er redusert. Mange flere får altså tilbud, og det er dokumentert signifikant bedring av symptomer og/eller funksjon for mer enn 50% av pasientene. (*Kates N, McPherson-Doe C, George L. 2011. Integrating mental health services within primary care settings. The Hamiton Family Health Team. J Ambulatory Care Management 34(2):174-182.)*

Dette samsvarer med en rapport fra Verdens helseorganisasjon om at ensidig satsing på spesialisthelsetjenesten reduserer levealder i befolkningen, mens sterkere satsing på primærhelsetjenesten øker befolkningens livskvalitet og livslengde. Hovedforfatter doktor Barbara Starfield fra Johns Hopkins School of Hygiene and Public Health i USA, hevder at samhandling nedenfra er det som skal til for å få kontroll på kostnadseksplosjonen. Vårt prosjekt vil undersøke om Starfields påstander stemmer med norsk virkelighet. Mens spesialisthelsetjenestens kostnader øker, er primærhelsetjenestens utgifter under kontroll.

Ideen i samhandlingsreformen er at en styrket og kompetent primærhelsetjeneste langt på vei vil dekke de samme behov for store pasientgrupper. Modellen som skal prøves ut i prosjektet er en konkretisering av samhandling, og nettopp en slik konkretisering er det som mangler for å bringe den planlagte samhandlingsreformen over fra en intensjon til faktisk endring av helsetilbudet for de store pasientgruppene som er omtalt i avsnittene nedenfor.

Mental helse Norge og andre brukerorganisasjoner har gjentatte ganger påpekt at myndighetene i for liten grad har fokus på tiltak for å bedre helsetilbudet for den store pasientgruppen med lettere eller moderat alvorlig psykisk sykdom (ofte depresjon og angst), som utgjør den største gruppen med psykiske plager i befolkningen og helsetjenestene.

Samhandlingsmodellen retter seg ikke minst mot pasienter med samtidig somatiske og psykiske helseplager, og med somatiske helseplager som uttrykk for ikke erkjente psykiske vansker. Dette er en pasientgruppe som ofte faller mellom flere stoler, og som en med samhandlingsmodellen i Canada har greid å fange opp i mye større grad enn ellers.

Et bedre helsetilbud for de nevnte store pasientgruppene vil kunne gi samfunnet store økonomiske innsparinger, ikke minst ved forebygging og reduksjon av mange og langvarige sykefravær. Samhandlingmodellen kan bidra til mer effektiv og riktigere bruk av helsepersonell både innen primærhelsetjenesten og spesialisthelsetjenesten. Registerkohortene i WP1 og WP3 er vesentlige for å kunne analysere og dokumentere dette (jfr nedenfor).

(B) REGISTERKOHORTENS BETYDNING
Registerkohorten i WP1 gjør det mulig å analysere hvordan arbeidsfordeling og samarbeid mellom primærhelsetjenesten og spesialisthelsetjenesten er for en stor gruppe pasienter som både har mye lidelse og representerer en stor kostnad for samfunnet. Vi kjenner ikke til at det i Norge tidligere er gjort en slik stor kvantitativ undersøkelse av pasientforløp og bruk av helsetjenester både i førstelinjetjenesten og psykisk helsevern på samme tid. Det er av vesentlig interesse for samfunnet å få slik ny kunnskap om status for arbeidsfordeling og samahandling mellom ulike helsetjenester, og for å få bedre grunnlag for å konkretisere en bedre samhandling.

Registerkohorten i WP3 i 2016 vil vise om en har oppnådd de ønskelig endringene i tilgjengelighet, pasientforløp og pasientfordeling ved etablering av «shared care» i 2015.

Den kliniske kohorten vil kunne gi svar på noen spørsmål som registerkohorten ikke kan svare på, fordi vi for den mer avgrensede kliniske kohorten får pasientenes egne utsagn om ulike forhold. Dette gjelder for eksempel andel pasienter med psykiske problemer (målt ved CORE-OM 10) der fastlegene ikke setter noen P-kode fra ICPC-2. Men det er registerkohorten vil vise hvor representativ den kliniske kohorten er, og dermed også om generaliserbarheten av funnene basert på den kliniske kohorten.

(C) ET ANNET PROSJEKT HAR FÅTT ADGANG TIL UTLEVERING AV DATA FRA FASTLEGERS JOURNALER PÅ SAMME MÅTE OG MED FRITAK FOR Å INNHENTE SAMTYKKE
Rx-PAD-studien om effekt av kollegabasert terapiveiledning for fastleger, er en cluster-randomisert studie med et stort antall fastleger, der en uten samtykke fra pasientene og med dispensasjon fra taushetsplikten fikk hente ut journalopplysninger fra fastlegen med samme metode som vi søker om, og koble disse til data i reseptregisteret, basert på fødselsnummer hentet fra pasientjournalen. Dette ble gjort ved lege/forsker Svein Gjelstad, som er med i vår forskningsgruppe og skal gjennomføre samme type datauttrekk for vår undersøkelse.

Det er altså tidligere gitt adgang til et annet prosjekt om å få utlevert data fra fastlegers elektroniske journaler og med fritak fra å innhente samtykke.

Vi vedlegger en artikkel (Gjeldtad 2013) fra den nevnte studien, der intervensjonen er beskrevet til høyre på side 2, og etisk godkjenning (REK-sør 05272 i 2005) er omtalt på side 6:
Ethical approval: Approval ID S-05272 from the Regional Ethics Committee South (“REK sør”) was obtained in 2005. The Rx-PAD study was approved by the Regional Committee for Research Ethics and by the Norwegian Social Science Data Services (NSD), which implied acceptance to extract the general practitioners’ prescription data. The Norwegian Directorate for Health and Social Affairs approved exception from health profession secrecy.
Trial registration: Clinical trials NCT00272155.

Også i den publiserte protokollen (Gjelstad 2006) fra den nevnte studien er godkjenningen omtalt øverst til venstre på side 8 i protokollen (Ethics and data security):
Participation is based on written informed consent from all physicians. The project has been presented for The Regional Committee for Research Ethics and approval from The Norwegian Social Science Data Services (NSD) has been obtained, implicating acceptance to extract prescription data. In order to use patient identification data in the merging process between NorPD and EPR databases, The Directorate for Health and Social Affairs has approved dispensation from the health-professional secrecy.

KONKLUSJON

Ut fra dette mener vi at prosjektet er av vesentlig interesse for samfunnet, og at REK kan bestemme at opplysninger i fastlegens journal kan utleveres til prosjektet i henhold til helseforskningsloven § 35 uten hinder av taushetsplikt, slik det er gjort i et tidligere prosjekt.

Vi vedlegger de to artiklene som er nevnt i teksten ovenfor om den studien som har fått data utlevert på tilsvarende måte fra fastlegers journaler uten krav om å innhente aktivt eller passivt samtykke.

3. Vedlegg

#	Type	Filnavn	Lagt inn dato
1.	Øvrige vedlegg	Gjelstad 2013 Artikkel.pdf	06.06.14
2.	Øvrige vedlegg	Gjelstad 2006 Study protocol.pdf	06.06.14

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	**Saksbehandler:**	**Telefon:**	**Vår dato:**	**Vår referanse:**
REK sør-øst	Anette Solli Karlsen	22845522	24.06.2014	2014/435/REK sør-øst A
			Deres dato:	**Deres referanse:**
			06.06.2014	

Vår referanse må oppgis ved alle henvendelser

Torleif Ruud
Avdeling forskning og utvikling, Divisjon psykisk helsevern, Akershus universitetssykehus

2014/435 Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personer med psykiske og andre sykdommer? Cluster randomisert studie

Vi viser til tilbakemelding på komiteens behandling av ovennevnte søknad. Opprinelig søknad ble behandlet i komitémøte 27.03.2014 og 08.05.2014. Klagen er behandlet i komitémøte 12.06.2014.

Forskningsansvarlig: Akershus universitetssykehus

Prosjektleder: Torleif Ruud

Opprinnelig prosjektbeskrivelse

Formålet med prosjektet er å undersøke hvorvidt en norsk tilpasning av en kanadisk modell med tverrfaglig helseteam kan gi et mer effektivt helsetilbud for personer med psykiske og andre sykdommer. Teamene skal bestå av fagpersoner fra primærhelsetjenesten og psykisk helsevern som samlokaliseres og samarbeider tett med fastleger.

Studien er delt i tre arbeidspakker, WP1-WP3. I WP1 skal nåværende praksis kartlegges ved å undersøke pasientforløp i en klinisk kohort som beskrevet nedenfor. I WP2 skal det brukes data fra WP1 til å identifisere behov for bedre samhandling og å utforme og implementere en norsk modell med felles helseteam. WP3 er en cluster randomisert studie der man skal undersøke om modellen med felles helseteam gir et mer effektivt helsetilbud enn dagens praksis.

Seks legesentre med 24 fastleger fra tre bydeler i Groruddalen er planlagt rekruttert til prosjektet.

Deltakerne skal deles i to kohorter; omtalt som klinisk kohort og registerkohort. Det totale antall deltakere i den kliniske kohorten er angitt til omlag 1350 pasienter.

Deltakere i den kliniske kohorten skal rekrutteres forløpende over 4 uker fra seks ulike legesentre. For disse skal det gjøres en samtykkebasert innhenting av definerte opplysninger fra fastlegejournal, NAV/HELFO samt Akershus universitetssykehus HF prospektivt 9 måneder etter inklusjon. Disse skal samtidig utfylle spørreskjemaer om blant annet psykisk helse, alkohol/rusmidler samt tilfredshet med de tjenester de har mottatt. Skjemaene skal utfylles 3 ganger i samme tidsrom. Deltakerne honoreres med Flax-lodd.

Som deltakere i registerkohorten søkes det om å inkludere alle pasienter som har vært til konsultasjon hos de 24 deltakende fastleger de siste 12 måneder. Det søkes om dispensasjon til å innhente opplysninger uten pasientens samtykke fra samme tidsrom fra fastlegejournal, NAV/HELFO og Akershus universitetssykehus HF.

Av søknadsskjemaet fremkommer det at man i prosjektet ønsker å koble mot data i Reseptregisteret. Prosjektleder har opplyst under saksforberedelsene at denne koblingen ikke er aktuell grunnet registerets pseudonymitet.

Saksbehandling

Søknaden ble behandlet i møte den 27.03.2014, og det ble fattet et utsettende vedtak.

Komiteen ba om tilbakemelding på følgende merknader før det fattes et endelig vedtak:

1. På generelt grunnlag bes det om en redegjørelse for hvordan de ulike opplysningene som innhentes i prosjektet skal knyttes opp mot studiens forskningsspørsmål innenfor de ulike arbeidspakkene.

2. Det må redegjøres for hvordan legesentre og fastleger er tenkt rekruttert til studien.

3. Det bes om en tilbakemelding på hvilke rutiner som skal følges når journalopplysninger skal innhentes fra fastleger og sykehus.

4. Spørreskjemaene CORE-10, CAGE-4 og CSQ-8 må ettersendes i norsk oversettelse. I «Shared care» skjemaet må utrykket ACT forklares.

5. Det bes om at det utarbeidede informasjonsskrivet revideres slik at studiens formål og metoder fremkommer på en tydeligere måte.

For den delen av prosjektet der man planlegger å innhente data fra journal og registre uten samtykke, den omtalte registerkohorten, bes det om en redegjørelse på følgende:

6. Hva den primære hensikten med og betydningen av registerkohorten er i prosjektet.

7. Det bes om en redegjørelse for hvilke opplysninger og variable som skal innhentes for disse pasientene- fra journal, sykehus og registre.

8. Det bes om en utfyllende begrunnelse for innhenting av de angitte opplysningene for alle pasienter som har vært til konsultasjon hos de aktuelle fastlegene siste 12 måneder.

9. Det bes om en begrunnelse for at man for registerkohorten skal innvilge dispensasjon fra taushetsplikt etter helseforskningsloven § 35.

For WP3 bes det om en redegjørelse for:

10. Hvordan clusterne skal randomiseres.

11. Hvorvidt det er lege eller pasient som er definert som «bruker».

12. Med hvilke variable man ønsker å besvare de angitte forskningsspørsmål (jf. «Research questions in WP3», s. 2 i vedlegget «Oversikt over data som skal samles inn og kobles»).

Prosjektleder har sendt tilbakemelding på komiteens merknader, denne ble mottatt 30.04.2014.

Av tilbakemeldingen fremkom det at to legesentre med samme størrelse er planlagt inkludert i prosjektet, hver med 4-5 fastleger. Det fremkommer at Mediata vil være ansvarlige for uthenting av journalopplysninger, fra legesentre og legevakt. Uthenting vil skje til en kryptert minnepinne som benyttes for overføring av data til en forskningsfil ved AHus.

Spørreskjemaene CORE-10, CAGE-4 og CSQ-8 ble vedlagt i norsk versjon. Informasjonsskriv ble revidert i forhold til komiteens merknader.

Som begrunnelse for å innhente data fra alle de aktuelle fastlegenes pasienter med fritak fra å innhente samtykke fra den enkelte pasient med hjemmel i helseforskningslovens § 35 argumenterte prosjektleder med at det vil være viktig å sammenligne antall og type henvendelser fra den enkelte fastlege før og etter implementering av «shared care» modellen. Som et resultat av «shared care» modellen kan man anta at det utvikles et bedre helsetilbud, som på sikt vil være av stor samfunnsmessig betydning i form av bedre utredning og behandling og da spesielt for utsatte pasientgrupper.

Til implementering av «shared care» modellen, redegjør prosjektleder for at det er planlagt inkludert seks legesenter i prosjektet, fra tre ulike bydeler. Av disse skal et legesenter i hver bydel randomiseres til «shared care» og da et legesenter i hver bydel som fortsetter vanlig praksis. Det fremkommer at det med bruker her menes pasienten.

Det ble gitt en oversikt over hvilke variable som skal knyttes opp mot de enkelte forskningsspørsmål.

Tilbakemeldingen ble behandlet i møte 08.05.2014, og det ble gitt en godkjenning på vilkår.

Komiteen anså prosjektleders tilbakemelding som tilfredsstillende i forhold til å besvare de merknader som tidligere har blitt anført vedrørende den kliniske kohorten. Komiteen hadde ingen innvendinger mot at denne delen av prosjektet blir gjennomført slik det fremkommer av søknad, protokoll og tilbakemelding.

Vedrørende det reviderte informasjonsskrivet er det ikke samsvar mellom formuleringene «Du vil kunne få et bedre helsetilbud» og «Det vil ikke ha noen innvirkning på helsetilbudet ditt dersom du ikke ønsker å delta». Komiteen ba om en justering av dette.

Når det gjelder prosjektleders tilbakemelding vedrørende den planlagte registerkohorten, anså komiteen det som inngripende ovenfor den enkelte pasient at deres fastlege skal utlevere opplysninger om sensitive forhold til forskning uten at det foreligger samtykke til dette. REK kan bestemme at helseopplysninger innsamlet i helse- og omsorgstjenesten kan utleveres til bruk i forskning, og at det kan skje uten hinder av taushetsplikt, jf. helseforskningsloven § 35. Dette kan bare skje dersom slik forskning er av vesentlig interesse for samfunnet og hensynet til deltakernes velferd og integritet er ivaretatt. Komiteen anså imidlertid ikke prosjektleders redegjørelse for betydningen av å innhente opplysningene som en tilstrekkelig begrunnelse for å gi fritak for å innhente samtykke til å bruke opplysningene uten at de aktuelle pasientene er gitt en mulighet til å reservere seg mot dette.

Komiteens godkjente i møte 08.05.2014 prosjektet med det vilkår at fastlegene som inngår i den planlagte registerkohorten informerer den enkelte pasient om at opplysninger fra journal er planlagt utlevert til forskningsprosjektet, og at den enkelte pasient gis anledning til å reservere seg mot at sine opplysninger utleveres. Komiteen ba om at det utarbeides et skriv med det formål å innhente passivt samtykke for deltakerne i registerkohorten med mulighet for reservasjonsadgang, og at dette innsendes til REKs arkiv.

Prosjektleder har påklaget vedtaket, i klage mottatt 06.06.2014.

Følgende forhold påklages:

1. Vilkåret om at fastlegene som inngår i den planlagte registerkohorten informerer den enkelte pasient om at opplysninger fra journal er planlagt utlevert til forskningsprosjektet.
2. Vilkåret om at den enkelte pasient skal gis anledning til å reservere seg mot at sine opplysninger utleveres til registerkohorten.

Prosjektleder argumenterer for at prosjektet er av vesentlig interesse for samfunnet og at REK derfor kan godkjenne at opplysninger i fastlegens journal kan utleveres til prosjektet.

Prosjektleder benytter tre argumenter for at prosjektet kan gjennomføres uten pasientenes samtykke, henholdsvis:

Prosjektet er av vesentlig interesse for samfunnet. Prosjektleder argumenterer for at modellen som skal prøves ut i prosjektet er en konkretisering av samhandling, som vil bidra til å bringe den planlagte samhandlingsreformen fra en intensjon til faktisk endring av helsetilbudet for den store pasientgruppen med lettere eller moderat alvorlig psykisk sykdom (ofte depresjon og angst)som utgjør den største gruppen med psykiske plager i befolkningen og helsetjenestene.

Om registerkohortens samfunnsmessige betydning hevder prosjektleder at denne gjør det mulig å analysere hvordan arbeidsfordeling og samarbeid mellom primærhelsetjeneste og spesialisthelsetjeneste er for en stor gruppe pasienter som både har mye lidelse og representerer en stor kostnad for samfunnet. Det er ikke tidligere gjort en slik stor kvantitativ undersøkelse av pasientforløp og bruk av helsetjenester både i førstelinjetjenesten og psykisk helsevern på samme tid. Det er av vesentlig interesse for samfunnet å få slik ny kunnskap om status for arbeidsfordeling og samhandling mellom ulike helsetjenester, og for å få bedre grunnlag for å konkretisere en bedre samhandling.

Videre viser prosjektleder til at et lignende prosjekt (saksnummer REK sør-øst 05275, tilrådd av REK i 2005) fikk godkjenning for utlevering av data fra fastlegers journal med fritak for å innhente samtykke.

Ny vurdering

Klagen ble behandlet i møte 12.06.2014.

Komiteen vurderer det slik at det i klagen ikke fremkommer nye opplysninger som danner grunnlag for en omgjøring av vedtaket av 22.05.2014.

Dispensasjon fra taushetsplikten etter helseforskningsloven § 35 kan bare gis dersom komiteen vurderer at forskningen er av vesentlig interesse for samfunnet og at deltakernes velferd og integritet er ivaretatt.

Prosjektleder har ikke gitt en god nok redegjørelse for hvorfor samfunnsinteressen overstiger ulempen for pasientene i dette prosjektet, utover å fremheve at samfunnsinteressen er meget stor. Etter komiteens syn er den planlagte tilnærmingen i prosjektet, å innhente opplysninger fra pasienter som benytter deltakende leger som fastlege, å anse som særdeles inngripende ovenfor den enkelte. Pasientens journal kan inneholde særdeles sensitive opplysninger som etter komiteens syn bør ha et høyt beskyttelsesvern.

Komiteen anser dette som et viktig prosjekt, og har derfor gitt prosjektleder anledning til å bruke opplysninger fra journal uten å måtte innhente aktivt samtykke, man da på det vilkår av at den enkelte pasient informeres og gis anledning til å reservere seg.

Vedtak

Komiteens vedtak av 22.05.2014 opprettholdes.

Prosjektleders klage sendes videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen,

Knut Engedal
Professor dr. med.
Leder

Anette Solli Karlsen
Komitesekretær

Kopi til: hilde.luras@ahus.no; postmottak@ahus.no

De nasjonale
FORSKNINGSETISKE
KOMITEENE

NEM • Den nasjonale
forskningsetiske komité for
medisin og helsefag

Kongens gate 14
0153 Oslo
Telefon 23 31 83 00

post@etikkom.no
www.etikkom.no

Org.nr. 999 148 603

Torleif Ruud
Akershus universitetssykehus

Vår ref.: 2014/160 Deres ref.:2014/435 Dato: 10.11.2014

Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personer med psykiske og andre sykdommer? Cluster randomisert studie.

Prosjektbeskrivelse i henhold til søknad

Prosjektet vil undersøke effekten av en norsk tilpasning til en kanadisk modell, som bygger på et tverrfaglig helseteam med fagpersoner fra primærhelsetjenesten og psykisk helsevern som samlokaliseres og samarbeider tett med fastleger. Man vil kombinere data fra pasienter om deres psykiske helse og tilfredshet med helsetjenesten, og registerdata om pasienter og bruk av tjenester fra fastleger, psykisk helsevern, kommunenes helsetjeneste og NAV. Seks legesentre med 24 fastleger fra tre bydeler i Groruddalen rekrutteres til prosjektet. Første del er en studie av dagens praksis. Pasientforløp undersøkes ved kombinasjon av data fra de nevnte helsetjenestene. I andre del brukes data fra første del til å identifisere behov for bedre samhandling, og å utforme og implementere en norsk modell med felles helseteam. Tredje del av prosjektet er en cluster randomisert studie for å se om modellen med felles helseteam (ved tre legesentre) gir et mer effektivt helsetilbud enn dagens praksis.

Tidligere saksbehandling

REK sør-øst A godkjente studien i brev datert 22.5.14 og gav fritak fra å innhente aktivt samtykke, men satte som betingelse at alle deltakerne skulle informeres med brev og gis reservasjonsadgang. REK sør-øst A gav følgende begrunnelse for pålegg om utsendelse av personlig brev med informasjon om studien og reservasjonsrett:
"Dispensasjon fra taushetsplikten etter helseforskningsloven § 35 kan bare gis dersom komiteen vurderer at forskningen er av vesentlig interesse for samfunnet og at deltakernes velferd og integritet er ivaretatt. Prosjektleder har ikke gitt en god nok redegjørelse for hvorfor samfunnsinteressen overstiger ulempen for pasientene i dette prosjektet, utover å fremheve at samfunnsinteressen er meget stor. Etter komiteens syn er den planlagte tilnærmingen i prosjektet, å innhente opplysninger fra pasienter som benytter deltakende leger som fastlege, å anse som særdeles inngripende ovenfor den enkelte. Pasientens journal kan inneholde særdeles sensitive opplysninger som etter komiteens syn bør ha et høyt beskyttelsesvern."

NEM tok saken første gang til behandling på komitémøtet 9.9.14. NEM viser til vedtak (datert 26.9.14) fra dette møtet for nærmere beskrivelse av saken og tidligere saksbehandling i REK. NEM anså prosjektets målsetting som svært sentral og viktig, men syntes imidlertid søknaden var mangelfull og uklar. Komiteen valgte derfor å invitere prosjektleder for å redegjøre nærmere for nødvendigheten av tilgang til alle pasientjournalene og for samfunnsnytten av prosjektet.

NEMs vurdering

NEM tok saken til annen gangs behandling på komitémøtet 28.10.14. Prosjektleder redegjorde for prosjektets helhet og oppklarte spørsmål rundt sammensetning og bruk av studiepopulasjonen. Det fremkom at hele materialet skal benyttes i begge delstudier, baseline og etter intervensjon. Begge kohortene består av en klinisk- og en register-populasjon. Pasientene som fyller ut spørreskjema bes om samtykke til å koble deres opplysninger til data fra pasientjournaler og registerdata, mens det søkes fritak fra å innhente samtykke fra registerpopulasjonen.

NEM støtter REKs vurdering av at prosjektets samfunnsnytte er stor. Det er viktig med forskning som kan legge til rette for bedre samhandling mellom primærhelsetjenesten og psykiatrien og prosjektet vil på sikt kunne bidra positivt for deltakerpopulasjonen. Prosjektet skal dessuten gjennomføres i en svært heterogen og stor populasjon i Groruddalen og etter komiteens vurdering vil dette øke den potensielle samfunnsnytten. NEM viser til REKs vurdering av potensiell integritetskrenkelse ved inklusjon uten samtykke. REK fremhever at det er særs sensitive data som krever høyt beskyttelsesvern. NEM oppfatter studien som mindre integritetskrenkende enn det REK legger til grunn for sitt vedtak. NEM anser ikke dataene som skal samles inn som særskilt sensitive og metoden for innhenting ivaretar deltakernes integritet. Et medisinsk datafirma (Mediata) vil være ansvarlige for uthenting av kodede journalopplysninger, fra legesentre og legevakt, data som så skal koples med informasjon fra NAV og psykiatrisk helsetjeneste. Uthenting vil skje til en kryptert minnepinne som benyttes for overføring av data til forskningsfilen. Det er primært diagnosekoder og resepter som hentes automatisk ut. Det er altså ikke snakk om at personer skal lese gjennom pasientjournalene, eller hente ut fritekst. NEM anser at fremgangsmåten er hensiktsmessig og at den ivaretar personvernet slik at integritetskrenkelsen blir minimert. Det skal inkluderes informasjon fra opp mot 30000 personer på fastlegenes lister hvorav vel 20000 vil ha hatt kontakt med helsetjenesten i løpet av ett år. Dette skal foretas i to omganger.

Hovedregelen er samtykke fra deltakere i helsefaglig forskning (hfl § 13). NEM har i sin praksis lagt til grunn at tre vilkår må være oppfylt for benyttelse av helseopplysninger i forskning uten samtykke (jf. hfl. §§ 15, 28 og 35).

1. Det er vanskelig å innhente samtykke
2. Forskningen er av vesentlig interesse for samfunnet
3. Deltakernes velferd og integritet skal ivaretas

NEM anser at alle tre kravene er tilfredstilt for registerpopulasjonen i omsøkte prosjekt, og opprettholder REKs fritak fra taushetsplikten slik at data kan tilgjengeliggjøres uten innhenting av aktivt samtykke, jf helseforskningslovens § 35.

Ved unntak fra samtykke gjelder personopplysningslovens bestemmelser om informasjonsplikt, jf. personopplysningsloven § 20, jf. helseforskningsloven § 2 tredje ledd. Hovedregelen ved fritak fra å innhente samtykke er at de involverte informeres om bruken av personopplysninger. NEM diskuterte unntak fra informasjonsplikten grundig. NEM anså det som spesielt viktig at hele populasjonen deltar i studien. Dette er en populasjon der en del har begrensete norskkunnskaper. Det er derfor utfordrende å få informert den aktuelle populasjonen tilfredsstillende. Personlige brev måtte i tilfelle utformes på en rekke ulike språk og sendes til nesten 30000 personer. Dette ble ansett som både praktisk vanskelig og uhensiktsmessig. Komiteen diskuterte om det var andre egnete måter å informere om deltakelsen, deriblant oppslag på legekontorene. Samlet vurdering var at slike oppslag kunne virke mot sin hensikt. Det ville være krevende å utforme et slikt oppslag på en måte som ville gi tilstrekkelig informasjon for den aktuelle populasjonen. NEM finner varsling uforholdsmessig vanskelig, slik at informasjon til de registrerte utgår i dette prosjektet.

Vedtak

Klagen godtas. Det gis databehandlingsgrunnlag for registerpopulasjonen uten innhenting av aktivt samtykke etter helseforskningslovens § 35 og uten krav om varsel til de registrerte, jf personopplysningsloven § 20 andre ledd bokstav b.

Hilsen

[redacted]

Dag Bruusgaard
Professor dr.med.
leder av NEM

Jacob C Hølen

Jacob C Hølen
sekretariatsleder i NEM, PhD

Kopi

Akershus universitetssykehus

REK

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	**Saksbehandler:**	**Telefon:**	**Vår dato:**	**Vår referanse:**
REK sør-øst A	Tove Irene Klokk	22845522	31.08.2020	25160
			Deres referanse:	

Torleif Ruud

25160 Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personer med psykiske og andre sykdommer? Cluster randomisert studie

Forskningsansvarlig: Akershus universitetssykehus HF

Søker: Torleif Ruud

REKs vurdering

Vi viser til søknad om prosjektendring datert 24.08.2020 for ovennevnte forskningsprosjekt (REK 2014/435). Søknaden er behandlet av sekretariatet i REK sør-øst på delegert fullmakt fra REK sør-øst A, med hjemmel i helseforskningsloven § 11.

Det søkes om å forlenge prosjektperioden, med ny sluttdato 31.12.2023.

Alle data er innsamlet, men det er behov for mer tid for analyser og publisering av resultatene. Oppdatert publiseringsplan er beskrevet i revidert forskningsprotokoll.

Sekretariatet har vurdert endringene og har ingen innvendinger mot at disse gjennomføres som beskrevet.

Vedtak

Godkjent

Komiteen godkjenner med hjemmel i helseforskningsloven § 11 annet ledd at prosjektet videreføres i samsvar med det som fremgår av søknaden om prosjektendring i samsvar med de bestemmelser som følger av helseforskningsloven med forskrifter.

Vi gjør samtidig oppmerksom på at etter ny personopplysningslov må det også foreligge et behandlingsgrunnlag etter personvernforordningen. Det må forankres i egen institusjon.

Godkjenningen gjelder til 31.12.2023.

Dersom det skal gjøres ytterligere endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende ny endringsmelding til REK.

Av dokumentasjonshensyn skal opplysningene oppbevares i 5 år etter prosjektslutt. Opplysningene skal oppbevares avidentifisert, dvs. atskilt i en nøkkel- og en datafil. Opplysningene skal deretter slettes eller anonymiseres.

Prosjektet skal sende sluttmelding til REK, se helseforskningsloven § 12, senest 6 måneder etter at prosjektet er avsluttet.

Vennlig hilsen

Jacob C. Hølen
Sekretariatsleder
REK sør-øst

Tove Irene Klokk
Seniorrådgiver
REK sør-øst

Kopi til forskningsansvarlig institusjon(er) og medbruker(e).

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK sør-øst A. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst A, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering.

Meldeskjema for tilrådning av forsknings- og kvalitetsprosjekter

Meldeskjemaet skal utfylles for

1) Kvalitetssikring
2) Medisinsk/helsefaglig forskning
3) Helsetjenesteforskning

som omfatter bruk av person- og helseopplysninger og humant biologisk materiale.

Mer informasjon: internettsiden til Ahus (Gå til www.ahus.no > Forskning og utvikling > Rutiner for forskning).

Utfylt skjema med vedlegg sendes til: personvern@ahus.no

A Prosjektopplysninger	
1 Prosjektleder ved Ahus (obligatorisk)	
Telefonnummer: 6796 8773 / 975 46 760	E-postadresse: torleif.ruud@ahus.no
Navn, stilling: Torleif Ruud, avdelingssjef	Avdeling: FOU-avdeling psykisk helsevern
2 Ekstern prosjektleder dersom prosjektet ledes av annen institusjon	
Navn, stilling:	Avdeling:
Telefonnummer:	E-postadresse:
3 Prosjektet er godkjent av forskningsansvarlig i divisjonen ved Ahus (obligatorisk)	
x Ja	
Navn, stilling: Øystein Kjos, divisjonsdirektør	Divisjon eller klinikk: Divisjon psykisk helsevern
4 Prosjekt tittel	
Norsk tittel: Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personermed psykiske og andre sykdommer? Cluster randomisert studie **Vitenskapelig tittel:** Is shared primary and mental health care better than current practice for people with mental and comorbid illnesses? Cluster randomized trial	
5 Prosjekt formål Gi en allment forståelig og kortfattet beskrivelse av bakgrunn og formål. Maksimalt 1000 tegn med mellomrom.	

Helsemyndigheter og brukere etterlyser bedre samhandling mellom primærhelsetjenesten og psykisk helsevern, men det er mangel på konkrete samhandlingsmodeller med godt dokumentert effekt.

Prosjektet vil undersøke effekten av en norsk tilpasning av en vellykket kanadisk modell med et tverrfaglig helseteam med fagpersoner fra primærhelsetjenesten og psykisk helsevern som samlokaliseres og samarbeider tett sammen med fastleggrupper. Vi vil kombinere data fra spørreskjema til fastlegepasienter (ved inklusjon i to uker og 3 og 9 måneder seinere) om deres psykiske helse og tilfredshet med helsetjenesten, og registerdata om pasienter og bruk av tjenester fra fastleger, psykisk helsevern, kommunenes helse- og sosialtjeneste og NAV. Seks legesentre med 24 fastleger fra tre bydeler i Groruddalen rekrutteres til prosjektet.

Første delprosjekt er en studie av dagens praksis. Pasientforløp undersøkes ved kombinasjon av data fra de nevnte helsetjenestene. I andre delprosjekt brukes data fra første del til å identifisere behov for bedre samhandling, og å utforme og implementere en norsk modell med felles helseteam. Tredje delprosjektet er en cluster randomisert studie av om modellen med felles helseteam (tre legesentre) gir mer effektivt helsetilbud enn vanlig praksis (tre legesentre). Datainnsamlingen fra pasienter og registre vil være den samme i første delprosjekt i 2015 (før cluster randomisering) og i tredje delprosjekt i 2017 (etter cluster randomisering). Helseteamene etableres høsten 2015 og skal arbeide gjennom hele 2016 før vi måler grad og betydning av endringer i 2017.

6 Prosjektperiode

Periode omfatter fra rekruttering til og med publisering.

Studiestart (dd.mm.åååå): 01.04.2015	Studieslutt (dd.mm.åååå): 30.06.2018	Slette tidspunkt for oppbevaring av opplysninger mht etterprøving (dd.mm.åååå): 30.06.2023

7 Andre prosjektopplysninger

a) Hovedformålet med prosjektet er:

☐ Kvalitetssikring
(Undersøke om etablert behandling/praksis gir de ønskede resultater)

X☐ Medisinsk/helsefaglig forskning
(Produsere ny vitenskapelig kunnskap om sykdom og helse)

☐ Annen forskning, inkludert Helsetjenesteforskning, som er utenfor REKs mandat for godkjenning

b) Relatert forskningsprosjekt:
(For eksempel tidligere prosjekt, hovedprosjekt, delprosjekt, parallellprosjekt)

X☐ Nei ☐ Ja, oppgi navn og personvern saksnummer. på prosjekt:

c) Internasjonalt samarbeid:

X☐ Nei ☐ Ja Hvis ja, kryss av:
☐ Del av internasjonal multisenterstudie
☐ Selvstendig datainnsamling i utlandet
☐ EU prosjekt

d) Utdanningsprosjekt/doktorgradsprosjekt:

X☐ Nei ☐ Ja Hvis ja, kryss av:
☐ Master ☐ Doktorgrad
☐ Annet, beskriv:

e) Finansiering:

☐ Interne strategiske forskningsmidler

X☐ Finansiert av avdelingen

X☐ Eksternt: Oppstartingsmidler for samhandlingsforskning tildelt fra Helse Sør-Øst i 2013.

Prosjektnummer/kostnadsted: Prosjektkommer 273932 Kostnadssted 900020

f) Prosjektmedarbeidere:

Navn, stilling, avdeling:

Torleif Ruud, avdelingssjef/professor, FOU-avdeling psykisk helsevern, Ahus
Ajmal Hussain, overlege/forsker ved Groruddalen DPS, Ahus
Ole Rikard Haavet, fastlege/førsteamanuensis, Avdeling for allmennmedisin, UiO
Mette Brekke, fastlege og professor, Avdeling for allmennmedisin, UiO
Svein Gjelstad, allmennlege og forsker, Avdeling for allmennmedisin, UiO
Mina Dahli, fastlegevikar, phd-kandidat
Jorun Rugkåsa, Helsetjenesteforskning, Ahus
Inger Cathrine Kann, Helsetjenesteforskning, Ahus
Hilde Lurås, Helsetjenesteforskning, Ahus
Dagfinn Bjørgen, landsleder, Mental helse Norge
Nick Kates, professor, McMaster University, Hamilton, Canada

B Informasjonssikkerhet

8 Samtykke

Skal det innhentes skriftlig samtykke fra den registrerte? X☐ Ja ☐ Nei

Hvis nei, begrunn hvorfor:

Skal det innhentes skriftlig samtykke fra stedfortredende ☐ Ja X☐ Nei

Hvis ja, av hvem:

Hvis barn inkluderes, angi alder:

Skal det søkes om unntak fra taushetsplikten? X ☐ Ja ☐ Nei

Hvis ja, begrunn hvorfor:

Nasjonal etisk komite (NEM) har godkjent unntak fra taushetslikten for innhenting av registerdata for fastlegepasienter (se godkjenning).

9 Detaljer om prosjektets informasjonsbehandling

9.1 Type personopplysninger databehandlingen / prosjektet skal omfatte:

(Flere avkrysninger mulig)

9.1.1 Ikke-sensitive personopplysninger

Identifikasjonsopplysninger

X☐ Navn, adresse, fødselsdato
X☐ Fødselsnummer (11 siffer)
☐ Fingeravtrykk, iris
☐ Annet:

9.1.2 Sensitive personopplysninger (jf. personopplysningsloven § 2 nr. 8)

Prosjektet omfatter opplysninger om

X☐ Rasemessig eller etnisk bakgrunn, eller politisk, filosofisk eller religiøs oppfatning
☐ At en person har vært mistenkt, siktet eller dømt for en straffbar handling
X☐ Helseforhold
☐ Seksuelle forhold
☐ Fagforeningstilhørighet

Presiser hvilke opplysninger som innhentes: Sosiodemografiske data, psykiske og fysiske helseproblemer, sykefravær, henvisninger mellom helsetjenester, bruk av helsetjenester, ytelser fra NAV.

9.2 Utvalg

(Flere avkrysninger mulig)

Behandlingen omfatter opplysninger om:

X☐ Pasienter ved Ahus
☐ Pårørende
X☐ Pasienter ved andre sykehus/ institusjoner
☐ Ansatte ved Ahus
☐ Elever/ studenter
☐ Andre, utdyp: Pasienter ved seks legesentre i Groruddalen.

9.3 Innsamling av opplysningene

Hvordan personopplysningene samles inn (flere avkryssinger er mulig)

X☐ Manuelt X ☐ Elektronisk (tekst, bilde, analysesvar) ☐ Videoopptak ☐ Lydopptak ☐ Annet (beskriv hvordan):

Hvor innhentes personopplysningene fra:

X☐ Fra den registrerte personlig.
X☐ Fra elektronisk system (journal/laboratorie/bildediagnostikk), angi hvilke: Hos fastleger, Ahus og NAV.
☐ Internt kvalitetsregister, angi hvilke:
☐ Forskriftsregulerte registre (eksempelvis fødselsregister, kreftregister eller dødsårsaksregister, eller interne konsesjonsbelagte registre). Angi hvilke registre: Norsk pasientregister
☐ Fra andre sykehus. Angi hvilke:
☐ Annet (beskriv hvor fra):

Hvis innsamlingen av personopplysninger skal utføres fra andre virksomheter, beskriv gjennomføring:

9.4 Uttrekk av helseopplysninger fra Ahus:

Hvem utfører uttrekk av helseopplysninger fra journal eller registre ved Ahus:

Den som utfører uttrekket må ha et ansettelsesforhold ved Ahus, eller på annen måte være under Ahus instruksjonsmyndighet og ha gyldig grunnlag for uttrekket.

☐ Prosjektleder eller prosjektmedarbeider.

X☐ Datafangstgruppen, send forespørsel til datafangst@ahus.no

☐ Andre – oppgi hvem:

9.5 Lagring og behandling av opplysninger

(Flere avkrysninger mulig)

Hvordan lagres opplysningene?

X☐ Forskningsserver ved Ahus

☐ Forskningsserver ved UiO (kun anonymiserte data)

X☐ På papir. Forklar hvordan dette sikres mot uvedkommende: Midlertidig oppbevaring i låste stålskap av samtykkeskjema og spørreskjema utfylt av pasienter til registerdata er innhentet og koblet. Data vil så bli anonymisert. Fødselsnummer oppbevares i egen liste atskilt fra avidentifiserte opplysninger om helsetilstand og behandling. Prosedyrene vil være de samme for de to datasettene fra 2015 og 2017, som ikke skal kobles på person og derfor vil bli anonymisert uavhengig av hverandre.

☐ På video, tape eller annet opptak. Beskriv hvordan dette er sikret og om personen kan identifiseres:

☐ Annet (for eksempel andre virksomheters nettverk). Beskriv:

9.6 Gjenfinning av opplysningene

a) Hvordan gjenfinnes opplysningene? (Bruk av direkte identifisering som personnummer og navn skal forsøkes unngått)

☐ Opplysningene lagres med navn, personnummer eller annet som entydig angir det enkelte individ

X☐ Opplysningene lagres avidentifisert (ved bruk av krysslister, kodenøkkel, løpenummer eller lignende)

b) Hvordan er krysslister/kodenøkler beskyttet/lagret?

☐ På papir, nedlåst på adgangsbegrenset rom på Ahus

X☐ Tilgangsstyrt prosjektområde på forskningsserver i sikker sone

☐ Annet, forklar:

c) Opplysningene er anonyme

☐ Anonyme opplysninger er informasjon som ikke på noe vis kan identifisere enkeltpersoner i et datamateriale, verken direkte gjennom navn eller personnummer, indirekte gjennom bakgrunnsvariabler, eller gjennom navneliste/koblingsnøkkel eller krypteringsformel og kode.

9.7 Utlevering av opplysningene

Blir personopplysningene gjort tilgjengelige/utlevert til andre samarbeidspartner(e) ☐ Ja X☐ Nei

Dersom ja:

Oppgi mottakers navn og adresse:

Er virksomheten innenfor EU/EØS: ☐ Ja ☐ Nei

Vil den eksterne virksomheten brukes som ressurs/laboratorium/annet for denne studien: ☐ Ja ☐ Nei

Vil mottakeren ha eget formål/studie: ☐ Ja ☐ Nei

Hva blir overført?

- ☐ Informasjon med navn, personnummer eller annet som entydig angir det enkelte individ
- ☐ Avidentifisert informasjon (kan identifiseres vha. en kode eller et løpenummer.)
- ☐ Anonymisert informasjon (kan ikke knyttes til en enkeltperson**)**

Hvordan oversendes informasjonen til andre virksomheter?

- ☐ Personlig overlevering
- ☐ Kryptert e-post (datafangstgruppen)
- ☐ Legges ut på sikret område for nedlasting av mottaker (kryptert)
- ☐ Registreres på sikret webserver, som ikke krever installasjon på Ahus-nett
- ☐ Annet. Beskriv nærmere:

10 Opprettelse av biobank / utførsel av materiale

10.1 Opprettelse eller bruk av eksisterende biobank, oppgi:

Forskningsbiobankens navn:

Ansvarshavende person:

Forskningsbiobankens innhold (vev, blod og lignende):

Antall givere:

Oppbevaringstid: fra til

Gjøres genetiske undersøkelser som har diagnostiske, prediktive eller behandlingsmessige konsekvenser for deltakeren? ☐ Ja ☐ Nei

Er genetiske opplysninger tenkt tilbakeført til deltakeren? ☐ Ja ☐ Nei

10.2 Utførsel av biologisk materiale til annen institusjon:

Institusjon og land:

Kontaktperson:

Akershus
universitetssykehus

Akershus universitetssykehus HF

Postadresse:
Postboks 95
1478 Lørenskog

Sentralbord:
02900

Org.nr:
NO 983 971 636 MVA

www.ahus.no

PERSONVERNOMBUDETS UTTALELSE

Til: Torleif Ruud, avd sjef forskning

Kopi: Øystein Kjos, div dir

Fra: Personvernombudet ved
Akershus universitetssykehus

Saksbehandler: Marianne B Blair

Dato: 13.05.15

Offentlighet: Ikke unntatt offentlighet

Sak: Personvernombudets uttalelse til innsamling og behandling av personopplysninger

Saksnummer/ Personvernnummer: 13-138

Personvernombudets uttalelse til innsamling og behandling av personopplysninger for forskning i prosjektet "*Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personermed psykiske og andre sykdommer*" (Shared care)

Prosjektbeskrivelse:
"Helsemyndigheter og brukere etterlyser bedre samhandling mellom primærhelsetjenesten og psykisk helsevern, men det er mangel på konkrete samhandlingsmodeller med godt dokumentert effekt.

Prosjektet vil undersøke effekten av en norsk tilpasning av en vellykket kanadisk modell med et tverrfaglig helseteam med fagpersoner fra primærhelsetjenesten og psykisk helsevern som samlokaliseres og samarbeider tett sammen med fastleggrupper. Vi vil kombinere data fra spørreskjema til fastlegepasienter (ved inklusjon i to uker og 3 og 9 måneder seinere) om deres psykiske helse og tilfredshet med helsetjenesten, og registerdata om pasienter og bruk av tjenester fra fastleger, psykisk helsevern, kommunenes helse- og sosialtjeneste og NAV. Seks legesentre med 24 fastleger fra tre bydeler i Groruddalen rekrutteres til prosjektet.

Første delprosjekt er en studie av dagens praksis. Pasientforløp undersøkes ved kombinasjon av data fra de nevnte helsetjenestene. I andre delprosjekt brukes data fra første del til å identifisere behov for bedre samhandling, og å utforme og implementere en norsk modell med felles helseteam. Tredje delprosjektet er en cluster randomisert studie av om modellen med felles helseteam (tre legesentre) gir mer effektivt helsetilbud enn vanlig praksis (tre legesentre). Datainnsamlingen fra pasienter og registre vil være den samme i første delprosjekt i 2015 (før cluster randomisering) og i tredje delprosjekt i 2017 (etter cluster randomisering). Helseteamene etableres høsten 2015 og skal arbeide gjennom hele 2016 før vi måler grad og betydning av endringer i 2017."

Viser til innsendt melding om behandling av personopplysninger / helseopplysninger. Det følgende er et formelt svar på meldingen. Forutsetningene nedenfor må være oppfylt før rekruttering av pasienter til studien kan starte.

Med hjemmel i Personopplysningsforskriftens § 7-12 jf. Personopplysningsloven § 31, har Datatilsynet, ved oppnevning av personvernombud, fritatt sykehuset fra meldeplikten til Datatilsynet. Forskningsprosjekter (studier) som omfatter høsting, lagring og tilgjengeliggjøring samt behandling av person-/helseopplysninger, meldes derfor til sykehusets personvernombud, se særlig helseregisterloven § 3 om formål og § 6 om alminnelige vilkår for å behandle helseopplysninger.

Personvernombudet har vurdert det til at den planlagte databehandlingen av personopplysninger / helseopplysninger tilfredsstiller de krav som stilles i helseforsknings- og personvernlovgivningen. Personvernombudet har ingen innvendinger til at den planlagte databehandlingen av personopplysninger / helseopplysninger kan igangsettes under forutsetning av følgende:

1. Forskningsansvarlig / databehandlingsansvarlig er Akeshus universitetssykehus HF ved adm. direktør.
2. Divisjonsdirektøren har godkjent gjennomføringen av prosjektet.
3. Behandling av personopplysningene / helseopplysninger (sensitive opplysninger) i prosjektet skjer i samsvar med og innenfor det formål som er oppgitt i meldingen.
4. Studien er vurdert av Regional komité for medisinsk og helsefaglig forskningsetikk (REK), er godkjent i Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) i brev av 10.11.14, og eventuelle merknader må følges.
5. Samtykke som er fremlagt benyttes for pasientene som skal rekrutteres in persona i forbindelse med konsultasjon. For pasienter som inkluderes indirekte, der man kun henter ut historiske opplysninger fra journal, blir det verken gitt informasjon eller innhentet samtykke og grunner seg på NEM sitt vedtak. NEM har vurdert prosjektleders begrunnelse for dette og gjort unntak fra taushets- og informasjonspliktene. REK sin tilbakemelding mht revidering av pasientinformasjon og –samtykke forutsettes etterkommet.
6. Data lagres som oppgitt i meldingen på tilgangsstyrt område på forskningsserver ved Ahus. Kodeliste som kobler avidentifiserte data (*indirekte identifiserbare helseopplysninger)* med personopplysninger lagres som angitt i meldingen og oppbevares separat nedlåst på adgangsbegrenset rom på sykehuset eller elektronisk som separat fil på tilgangsstyrt prosjektområde på forskningsserver i sikker sone. Kontakt datafangstgruppen for opprettelse av prosjektområde på forskningsserver på datafangst@ahus.no
7. Prosjektslutt er 30.06.2018. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 30.06.2023 (sluttdato 5år for vanlige prosjekter), da skal data slettes eller anonymiseres ved at kodelisten slettes og eventuelle andre identifikasjonsmuligheter i databasen fjernes (senest 6 mnd etter sluttdato dvs 31.12.2023) i hht samtykke fra REK. Når det gjelder pasienter rekrutterte in persona så vil kodelisten slettes 9 måneder etter mottak av siste skjema, i motsetning til dem som inkluderes indirekte (registerpopulasjon uten krav til aktivt samtykke eller iformasjon) og i hht samtykke fra NEM. Personvernombudet bes orientert om at begge slettedatoer er overholdt.
8. Det må etableres en databehandleravtale med de inkluderte legesentrene i de tre bydelene i Oslo, som skal utlevere pasientdata til Ahus, samt andre offentlige instanser som NAV/HELFO, fordi helseopplysninger skal utleveres, se helseregisterloven § 6 annet ledd, personopplysningsloven § 2 nr 5 og

personopplysningsforskriften § 7-12. Eksterne som skal utlevere data til Ahus har rett til å få innsyn i risikovurderingen som er gjort for forskningsserveren på Ahus. Det anbefales å kontakte Datafangstgruppen for bistand til dette.

9. Dersom formålet, utvalget av inkluderte eller databehandlingen endres må personvernombudet gis forhåndsinformasjon om dette i likhet med REK/NEM.

Studien er registrert i sykehusets offentlig tilgjengelig database over forsknings- og kvalitetsstudier.

Lykke til med studien!

Med vennlig hilsen

[redacted]

Marianne B Blair
Personvernombud
Akershus universitetssykehus HF

Epost: personvern@ahus.no
Web: www.ahus.no

AKERSHUS UNIVERSITETSSYKEHUS

Akershus universitetssykehus HF

Postadresse:
Postboks 95
1478 Lørenskog

Sentralbord:
02900

Org.nr:
NO 983 971 636 MVA

www.ahus.no

PERSONVERNOMBUDETS UTTALELSE

Til:	Torleif Ruud, professor emeritus Akershus Universitetssykehus HF
Kopi:	Ketil Hanssen-Bauer, avdelingsleder Avdeling for forskning og utvikling Divisjon for psykisk helsevern Akershus Universitetssykehus HF
Fra:	Personvernombudet ved Akershus Universitetssykehus HF
Dato:	10.09.2020
Offentlighet:	Ikke unntatt offentlighet
Sak:	Personvernombudets uttalelse i forbindelse med endringsmelding.
Saksnummer/ Personvernnummer:	Saksnummer: 16/05462 Personvernnummer: 2013_138

Personvernombudets uttalelse i forbindelse med endringsmelding i prosjektet «Er felles primærhelsetjeneste og psykisk helsevern bedre enn nåværende praksis for personer med psykiske og andre sykdommer? Cluster randomisert studie»

Viser til innsendt endringsmelding i ovennevnte prosjekt. Det følgende er et formelt svar på meldingen.

Endringene består i endring av dato for prosjektslutt til 31.12.2023.

Personvernombudet anbefaler at ovennevnte endringer gjennomføres under forutsetning av at prosjektslettedato er i samsvar med REK-godkjenning av endringsmeldingen.

Det forutsettes imidlertid at personvernet fortsatt ivaretas slik som beskrevet i opprinnelig uttalelse fra personvernombudet.

Med vennlig hilsen
for personvernombudet

Hans Tangen
Personvernrådgiver/Jurist
Akershus universitetssykehus HF

Epost: forskning.personvern@ahus.no
Web: www.ahus.no

Errataliste

Kandidat: Mina Piiksi Dahli

Avhandlingstittel: Mental health problems in Norwegian general practice. Identification, presentation, diagnosis.

Side	Linje	Fotnote	Originaltekst	Type rettelse	Korrigert tekst
5	9		… In addition, physical and somatic …	Cor	… In addition, psychological and somatic …
11	18		… increase in somatic symptom diagnosis …	Cor	… increase in somatic symptom diagnoses …
11	21		… symptoms diagnoses received …	Cor	… symptom diagnoses received …
13	3		… fysisk helseplager …	Cor	… fysiske helseplager …
14	24		.. 74,3 % …	Cor	… 73,3 % …
45			3.5.2 Somatic symptoms diagnoses	Cor	3.5.2 Somatic symptom diagnoses
56	4		… We found that 74,3 % of patients …	Cor	… We found that 73,3 % of patients …
60	20		… significant increase in somatic symptom diagnoses compared to …	Cor	… significant increase in somatic symptom diagnoses comparable to …