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Development of a model for shared care between general practice and mental healthcare: a protocol for a co-production study

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ABSTRACT

Introduction Mental health illness represents one of the greatest health burdens in the world. It is well documented that treatment of these illnesses could be optimised through strengthened collaboration between general practice and specialised mental healthcare services (shared care). Furthermore, involvement of users in the design of new interventions to strengthen end-user value and sustainability is key. Therefore, the aim of this study is to develop a shared care intervention in co-production with users.

Methods and analysis The study will take place at psychiatric outpatient clinics in Denmark.
The project is described in four sequential steps, each informing and leading into the next: a systematic review (step 1) will be followed by an exploratory study investigating how stakeholders (general practitioners, mental healthcare staff and patients) perceive existing treatment and collaboration between general practice and mental health services. Steps 1 and 2 will inform and qualify the intervention that will be developed in step 3 as a co-creation study. Step 4 will assess the intervention in a feasibility study. Step 4 will be designed as a non-randomised intervention study with a control group with preassessments and postassessments. In total, 240 patients will be recruited. Questionnaires will be administered to the participants at their first visit to an outpatient clinic and again after 3 months. The primary outcome will be patients' self-reported mental health status (Short Form Health Survey, SF-36) and recovery (revised Recovery Assessment Scale, RAS-R). Recruitment will take place from June 2023 to May 2024.

Ethics and dissemination The project is approved by the ethics committee (REG-016–2022). Informed consent based on written and verbal information about the aims, purpose and use of the study and the data collection will be obtained from all participants. The study findings will be published in peer-reviewed journals and presented at national and international conferences. The study is registered at ClinicalTrials.gov.

Trial registration number NCT05172375.

Prospero registration number 287989.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ In this study, there will be a high level of user involvement to gain a greater understanding of stakeholders' perspectives on interprofessional collaboration, treatment and recovery processes.
⇒ This study will be conducted in co-production with users to help create a deeper understanding for all parties involved and to strengthen end-user value and sustainability.
⇒ Owing to the nature of the study design, we will be unable to randomise blind patients to treatment groups.
⇒ The findings in the intervention study will be based on self-reported measures, and it is possible that individual's perception of their illness may differ.

INTRODUCTION

Recent research has indicated that the mental health of people with depression and anxiety has deteriorated over the last decades, in Denmark as well as globally, and has reached a level where it is perceived to be a global health challenge.[1–3] Depression and anxiety affect individuals' psychosocial well-being and occupational functioning[4 5] and are increasingly the cause of sick leave in high-income countries.[6] Currently, depression is the most common health ground for early retirement in Denmark.[7] Early intervention for patients with depression and anxiety is essential, also because research further shows that many young people with mental health difficulties drop out of education and work.[8 9] Yet it appears that people with mental health difficulties do not receive adequate and sufficient support and treatment.[10 11] Even though shared care between general practice and mental health service was initiated in Denmark more than 10 years ago,[12] the collaboration between the two sectors continues to be challenged.[13] Several logistic and organisational challenges affect the collaboration, for example, inadequate referral procedures and increased workload for general practitioners (GPs).[14–16] Møller *et*

al also emphasise that GPs and patients should be key in the development of future collaborative care models.[14] General practice remains central in the course of treating anxiety and depression, as the majority of people with these disorders are diagnosed and treated in the primary care sector.[12] Among international researchers, there is consensus that while treatment could be optimised through strengthened collaboration between general practice and specialised mental healthcare services, the majority of patients should continue to be treated in general practice.[17] Thus, a renewed focus on shared care is needed.[18] Shared care enables a 'best of both worlds' scenario (ie, primary care and specialised mental healthcare services) with the opportunity to provide high-quality holistic care to support the recovery process of people with mental health difficulties. Shared care aims at bringing together interprofessional expertise to enable enhanced creativity in problem solving.[19] It also aims to decrease the number of patients 'left in limbo' between the primary and secondary care sectors, with both patients and carers feeling that they are failing to make progress through the healthcare system.[19] Previous studies have found that shared care interventions significantly improve treatment outcomes compared with treatment as usual.[20 21] In a situation where researchers, patients and policymakers continue to push for the adoption of shared care between general practice and mental health services[22] and bearing in mind that the most recent review is almost 10 years old, we believe that a systematic review of recent studies of shared care is timely, notably to provide a synthesis of the best available evidence for recommendations on future shared care interventions. The project is committed to a high level of user involvement to support learning for all parties involved[23] and furthermore to strengthen end-user value and implementation. Involving users in the study will enhance our understanding of stakeholders' perspectives in relation to collaboration between general practice and mental health services. It is also the assumption that a shared care approach strengthens both treatment and social support, and thereby supports the recovery process of people with mental illness. The overall aim of this study is to develop a shared care intervention in co-production with users.

In accordance with co-production research design, this project will be initiated by a group of stakeholders involved in shared care. They will explore and share their personal experiences and ideas in collaboration with professionals and researchers.

METHODS AND ANALYSIS

A basic assumption in this study is that a research partnership can grow out of a co-production process.[24] The co-production process will be conducted with a four-step approach inspired by the Medical Research Council (MRC) framework for developing and evaluating complex interventions[25]—describing four sequential steps, each informing and leading into the next step: a systematic review (step 1) will be followed by an explanatory study (step 2) with interviews of relevant stakeholders in shared care to explore how general practitioners, mental health staff and patients perceive collaboration, user involvement and the course of treatment in shared care. The results from the systematic review will inform the planning and preparation of step 2, and both steps will inform and qualify the intervention (steps 3 and 4). In the third step, workshops will be organised with the aim of discussing, refining and gaining consensus on the developed shared care model to systematically capture and incorporate stakeholders' suggestions for the intervention and adaptation along the project.

Participants

To be included, participants should be adults aged 18–65 years, diagnosed with depression or anxiety and referred to an outpatient psychiatry clinic. Furthermore, general practitioners and professionals from mental health services will be included.

Organisation

The study will be organised with a steering group, who will provide organisational anchoring and ensure scientific rigorousness, and a project group, who will conduct day-to-day operations. Both groups will be composed of users with experiences from mental health services, health professions and research. The steering group will have the overall responsibility for implementing the intervention in accordance with the protocol description, deciding on changes, approving the framework and resources. The project group will be responsible for day-to-day operations, including ensuring that stakeholders are involved in the process, providing information about the study, conducting the intervention, performing impact assessments and applying for external funds. Furthermore, ad hoc working groups will be held continuously during the project. All groups include patients, professionals and trained researchers. Patients in the steering and project group will be recruited from the mental health service user panels of the included region.

Step 1: systematic review

A group of stakeholders and researchers will conduct a systematic literature review with the aim to inform the development of the intervention (step 3). A narrative systematic review will be conducted based on the following research questions: (1) What characterises a shared care model? (2) How do general practitioners, mental healthcare providers and patients experience shared care? The review will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[26] We will conduct a search in the Medline, CINAHL, PsychINFO and EMBASE databases for both qualitative and quantitative studies published between January 2001 and January 2022. Two independent researchers (MM and BN) will conduct screening at both the title and abstract level, and disagreements will

be resolved through discussion or via the involvement of a third author (LB). Full-text reading and quality assessment (risk of bias) will be based on Clinical Appraisal Skills Programme checklists.[27] The project is registered in PROSPERO (287989) and will be carried out using the Covidence software platform (covidence.org).

Step 2: user perspectives on shared care (gap analysis)

We will include stakeholders' experiences of their course of treatment to develop a new model of shared care for the benefit of the patients. A group of stakeholders and researchers will analyse the transcribed interviews thematically[28] in order to identify the patients, GPs and mental healthcare providers' experiences and needs of support in relation to shared care. Step 2 will be an exploratory study based on interviews with experts involved in shared care, general practitioners, patients and healthcare professionals from the mental healthcare service. The interviews will be conducted to investigate what people with mental illness and health professionals find important in the treatment process, as well as to elicit their perspectives on shared care, collaboration and recovery. Informants will be found with a view to maximal variation in terms of age, sex, profession, diagnosis and duration of illness. A semistructured interview guide will be prepared and informed by the results from step 1, and data analysis will be based on thematic analysis, inspired by Coffey and Atkinson.[28] The patient participants will be adults aged 18–65 years, diagnosed with depression or anxiety and referred to an outpatient clinic. The healthcare professionals will be recruited from the two outpatient clinics to which the patients are referred. General practitioners will be recruited through purposive sampling, and informants will be selected with a view to capturing variation across sex, age, years of experience, practice type (individual practice/partnership) and geographic location.

Step 3: development of the intervention (co-production)

Patient and public involvement based on workshops

Building on the previous steps, this study will focus on the development of an intervention in co-production with users. In co-production, knowledge creation is a joint venture among users and researchers[23] who work together to create relevant and practice-oriented knowledge.[29–31] The involvement of patients in all steps will result in greater relevance for both clinical practice and patients.[29] The new shared care intervention will be developed in co-production with the users. Co-production in research is defined as 'an approach in which researchers, practitioners and the public work together, sharing power and responsibility from the start to the end of the project, including in the generation of knowledge'.[32] Here, patients and healthcare professionals are both defined as users. In this approach, the researchers are responsible for the scientific processes. Users are responsible for bringing their experiences into the process. Likewise, the professionals are responsible for learning and testing the interventions. Together, this enables the production of 'informed interventions'.[31] In this study, both researchers and users (patients and healthcare professionals from mental health services and/or general practice) will commence with workshops where they will share, discuss and decide on the intervention and discuss relevant knowledge from the review and from the interviews (steps 1 and 2). A group of stakeholders and researchers will meet and share relevant knowledge from the interview study. More than half of the attending participants will be patients, towards whom the interventions will be directed. The attendees will create the first draft of the intervention and suggest the relevant outcomes. Hereafter, meetings for reflection on experiences will be organised, and the intervention will be shaped and adjusted accordingly.[31] The findings from the previous stages are followed by a final expert review as recommend in the MRC framework.[25] In step 4, the intervention will be tested.

Step 4: feasibility study

Study design

The study will be designed as a non-randomised intervention study with a control group. Comparative analysis of the two groups will be conducted with preassessments and postassessments (quasi-experimental design). The design enables the comparison of change over time between the two groups (intervention vs comparison group), and this quasi-experimental design can be applied in real-world setting,[33] which subsequently can strengthen the implementation in clinical practice. Furthermore, we will adjust for potential confounders in the statistical analyses to minimise bias of the findings.[33]

Setting and participants

The participants will be adults aged 18–65 years, diagnosed with depression or anxiety, and referred to an outpatient psychiatry clinic. As part of the publicly funded hospital services, the mental health services are administered by one of Denmark's five regional health authorities.

Patients will be recruited over a 12-month period from June 2023 to May 2024. The patients are referred to outpatient clinics based on their home address. Thus, the two outpatient clinics should be comparable in terms of patients' diagnoses and staffing. The trial is registered at ClinicalTrials.gov (NCT05172375) and will adhere to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (spirit-statement.org).

Intervention

Shared care is a collaboration between general practice and mental health services and enables a 'best of both worlds' scenario with the opportunity to provide high-quality holistic care to support the recovery process of people with mental health difficulties.[19] The founder of the shared care model (the Canadian Collaboration Mental Health Initiative) defined shared care as 'collaborative mental healthcare models of practice in which consumers, their families and caregivers, together with healthcare providers from a variety of

primary healthcare and mental health settings—each with different experience, training, knowledge and expertise—work together to provide better coordinated and more effective services for individuals with mental health needs'.[34] These services include mental health promotion, illness prevention, detection and treatment of mental illnesses, rehabilitation and recovery support. Shared care can encompass a broad range of activities, such as regular visits by a mental healthcare worker to a primary healthcare setting and regular telephone consultations between primary healthcare and mental healthcare providers. Furthermore, this approach includes interprofessional care providers such as psychiatrists, psychologists, nurses, social workers and occupational therapists from a community setting. Due to the interdisciplinary nature of the treatment, joint treatment plans formed by users and providers are essential for incorporating mental health interventions into the management of general medical conditions.[15]

The final version of the intervention will be based on the results of steps 1–3.

Patients in the control group will receive treatment as usual. The control group patients will be referred to a psychiatric outpatient clinic that offers standard uniprofessional care without any formalised collaboration with general practice.

Primary outcomes

The primary outcomes will be the patient's mental health status and recovery. Mental health status is a valid and reliable indicator of a patient's self-reported mental state and well-being.[35] Mental health status will be assessed using the standardised Short Form Health Survey (SF-36), first developed in the USA by Ware *et al*.[36] For decades, the SF-36 questionnaire has been commonly used as a generic tool for measuring health status (functional health and well-being)[37] and has also been used in Denmark.[38] The Danish translation of the original English-language version will be used. Furthermore, the patients' recovery will be assessed by the 24-item revised Recovery Assessment Scale (RAS-R).[39]

Secondary outcomes

The study will have five secondary outcomes: (1) patient level of function, which will be assessed by using the Global Assessment of Functioning tool.[40] Patient satisfaction measured with (2) the Client Satisfaction Questionnaire (CSQ-8)[41] and with (3) the Quality-of-Life Enjoyment and Satisfaction Questionnaire.[42] The improvement in collaboration between general practice and mental health will be assessed with (4) the Collaborative Practice Scale[43] and with (5) the Shared Decision-Making Questionnaire (SDM-Q9).[44] All translations of scales have been validated in a Danish population. The outcome measures are listed in table 1. The implementation of the shared care model will be monitored by fidelity assessments.

Table 1 Patient characteristics and outcomes

Variable	Baseline	3-month follow-up
Age	X	
Sex	X	
Outpatient clinic	X	
Mental health status	X	X
Recovery	(X)	X
Level of function	X	X
Patient satisfaction		X
Shared care collaboration	X	X
Shared decision making	X	X

Procedure for data collection

The questionnaires will be administered to the participants at their first visit to the outpatient clinic (baseline) and again after 3 months (follow-up) (figure 1). Patients who do not consent to participate or fail to complete the questionnaire at the first visit to the outpatient clinic will be excluded. Data as described in table 1 will be collected. The inter-rater reliability will be tested using test-retest and percentage of agreement. There will be a procedure to ensure that the collection of data at baseline and follow-up will be performed by different people. If the patient is no longer available, the reason will be identified (loss to follow-up).

Sample size

The sample size calculation is based on an intervention study with SF-36 as the primary outcome; this calculation was previously used in a mental health services study.[35] In the proposed study, there will be a clinically relevant effect size of 0.5 with a power of 80 (α=0.05). Based on the sample size calculation and anticipating a withdrawal rate of 20%, 120 patients in each group (intervention and control) will be needed.

Data analysis

Descriptive analysis

Categorical data will be presented as numbers and proportions; continuous variables will be presented as medians and quartiles. Baseline data will be compared between the groups. The chi-square test or Fisher's exact test will be used for the analysis of categorical variables. Analysis of variance and the Kruskal-Wallis's test will be used for non-parametric and non-normally distributed variables, respectively.

Primary and secondary analyses

All analyses will be conducted based on the intention-to-treat principle. Missing outcomes will be imputed, and for non-adherence to protocol, a per-protocol analysis will be conducted as a sensitivity analysis. A non-response analysis will be carried out for excluded patients and non-completers.

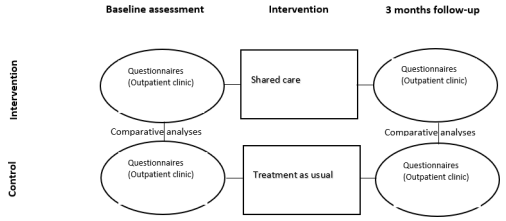

Figure 1 Study design.

Process evaluation

A process evaluation based on a programme theoretical method will be conducted to identify facilitators and barriers for the shared care model. The method is based on the various stakeholders' perspectives on how shared care can be implemented.[45]

ETHICS AND DISSEMINATION

Information of the participants and data management will be treated in accordance with the Helsinki Declaration.[46] Informed consent to participate in the study will be obtained from all participants. Before inclusion, participants will receive information, both written and verbally, about the purpose of our study, contact information, anonymity, confidentiality and the responders' right to withdraw from the study at any time (online supplemental material). Furthermore, all participants will be informed that their participation is voluntary, that they can withdraw their consent at any time without consequences and that their statements will be anonymised and treated confidentially. Data will be entered into the EasyTrial Online Clinical Trial Management system. All personal identifiers will be removed or disguised during analysis to preclude personal identification. The project is approved by the Research Committee of Region Zealand (REG-016–2022), in agreement with both research ethics and General Data Protection Regulation (GDPR).[47] In addition to the clinical implementation, the project results are expected to be published in international journals and disseminated at national and international conferences. Included organisations will be credited with any form of dissemination of both preliminary and final results.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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REFERENCES

1 Christensen TN, Wallstrøm IG, Bojesen AB, *et al*. Predictors of work and education among people with severe mental illness who participated in the Danish individual placement and support study: findings from a randomized clinical trial. *Soc Psychiatry Psychiatr Epidemiol* 2021;56:1669–77.
2 Mojtabai R, Olfson M, Han B. National trends in the prevalence and treatment of depression in adolescents and young adults. *Pediatrics* 2016;138:e20161878.
3 World Health Organisation (WHO). *World mental health report: transforming mental health for all*. Geneva, 2022.
4 Kennedy N, Foy K, Sherazi R, *et al*. Long-term social functioning after depression treated by psychiatrists: a review. *Bipolar Disord* 2007;9:25–37.
5 Iancu SC, Batelaan NM, Zweekhorst MBM, *et al*. Trajectories of functioning after remission from anxiety disorders: 2-year course and outcome predictors. *Psychol Med* 2014;44:593–605.
6 Rugulies R, Aust B. Work and mental health: what do we know and how can we intervene? *Scand J Work Environ Health* 2019;45:529–32.
7 Søgaard HJ, Bech P. Psychiatric disorders in long-term sickness absence -- a population-based cross-sectional study. *Scand J Public Health* 2009;37:682–9.
8 Manthey TJ, Goscha R, Rapp C. Barriers to supported education implementation: implications for administrators and policy makers. *Adm Policy Ment Health* 2015;42:245–51.
9 Ringeisen H, Langer Ellison M, Ryder-Burge A, *et al*. Supported education for individuals with psychiatric disabilities: state of the practice and policy implications. *Psychiatr Rehabil J* 2017;40:197–206.
10 Hunt J, Eisenberg D. Mental health problems and help-seeking behavior among college students. *J Adolesc Health* 2010;46:3–10.
11 Weitkamp K, Klein E, Midgley N. The experience of depression: a qualitative study of adolescents with depression entering psychotherapy. *Glob Qual Nurs Res* 2016;3:2333393616649548.
12 Bauer J, Okkels N, Munk-Jørgensen P. State of psychiatry in Denmark. *Int Rev Psychiatry* 2012;24:295–300.
13 Byng R, Norman I, Redfern S, *et al*. Exposing the key functions of a complex intervention for shared care in mental health: case study of a process evaluation. *BMC Health Serv Res* 2008;8:274.
14 Møller MCR, Mygind A, Bro F. Who needs collaborative care treatment? A qualitative study exploring attitudes towards and experiences with mental healthcare among general practitioners and care managers. *BMC Fam Pract* 2018;19:78.
15 Overbeck G, Kousgaard MB, Davidsen AS. The work and challenges of care managers in the implementation of collaborative care: a qualitative study. *J Psychiatr Ment Health Nurs* 2018;25:167–75.

16 Curth NK, Brinck-Claussen Ursula Ødum, Hjorthøj C, *et al*. Collaborative care for depression and anxiety disorders: results and lessons learned from the Danish cluster-randomized Collabri trials. *BMC Fam Pract* 2020;21:234.
17 Magaard JL, Liebherz S, Melchior H, *et al*. Collaborative mental health care program versus a general practitioner program and usual care for treatment of patients with mental or neurological disorders in Germany: protocol of a multiperspective evaluation study. *BMC Psychiatry* 2018;18:347.
18 Bower P, Gilbody S. Managing common mental health disorders in primary care: conceptual models and evidence base. *BMJ* 2005;330:839–42.
19 Lester H. Shared care for people with mental illness: a GP's perspective. *Advances in Psychiatric Treatment* 2005;11:133–9.
20 Hardwick R, Pearson M, Byng R, *et al*. The effectiveness and cost-effectiveness of shared care: protocol for a realist review. *Syst Rev* 2013;2:12.
21 Overbeck G, Davidsen AS, Kousgaard MB. Enablers and barriers to implementing collaborative care for anxiety and depression: a systematic qualitative review. *Implement Sci* 2016;11:165.
22 Ladefoged U, Højmark A, Universitet A. Integrerede indsatser for mennesker med psykiske lidelser - En forskningsoversigt. *Mental Health Nursing* 2017.
23 Berring LL, Hummelvoll JK, Pedersen L, *et al*. A co-operative inquiry into generating, describing, and transforming knowledge about De-escalation practices in mental health settings. *Issues Ment Health Nurs* 2016;37:451–63.
24 Hostick T, McClelland F. 'Partnership': a co-operative inquiry between community mental health nurses and their clients. 2. The nurse-client relationship. *J Psychiatr Ment Health Nurs* 2002;9:111–7.
25 Skivington K, Matthews L, Simpson SA, *et al*. A new framework for developing and evaluating complex interventions: update of medical Research Council guidance. *BMJ* 2021;374:n2061.
26 Page MJ, McKenzie JE, Bossuyt PM, *et al*. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71.
27 CASP. *Critical appraisal skills programme: making sense of evidence about clinical effectiveness: 11 questions to help you make sense of a trial*, 2010: 1–3. http://www.casp-uk.net/wp-content/uploads/2011/11/CASP_RCT_Appraisal_Checklist_14oct10.pdf
28 Coffey A, Atkinson P. *Concepts and coding. in: making sense of qualitative data*, 1996.
29 Hybholt L, Buus N, Erlangsen A, *et al*. Psychosocial rehabilitation of elderly persons bereaved by suicide: a co-operative inquiry study protocol. *Issues Ment Health Nurs* 2019;40:382–90.
30 Berring LL, Buus N, Hybholt L. Exploring the dynamics of a research partnership in a co-operative inquiry: a qualitative study. *Issues Ment Health Nurs* 2021;42:818–26.
31 Hummelvoll JK, Severinsson E. Researchers' experience of co-operative inquiry in acute mental health care. *J Adv Nurs* 2005;52:180–8.
32 Bortoli S. *Guidance on co-producing a research project*, 2021.
33 de Vocht F, Katikireddi SV, McQuire C, *et al*. Conceptualising natural and Quasi experiments in public health. *BMC Med Res Methodol* []. 2021;21:32.
34 Kates N, Ackerman S, Crustolo AM, *et al*. *Collaboration between mental health and primary care services*, 2006.
35 Richards DA, Hill JJ, Gask L, *et al*. Clinical effectiveness of collaborative care for depression in UK primary care (CADET): cluster randomised controlled trial. *BMJ* 2013;347:f4913.
36 Ware JE, Snow KK, Kosinski M. *Sf-36 health survey manual and interpretation guide*. The Health Institute, Boston New England Medical Centre, 1993.
37 Guilfoyle MR, Seeley H, Laing RJ. The Short Form 36 health survey in spine disease--validation against condition-specific measures. *Br J Neurosurg* 2009;23:401–5.
38 Bjorner JB, Thunedborg K, Kristensen TS, *et al*. The Danish SF-36 health survey: translation and preliminary validity studies. *J Clin Epidemiol* 1998;51:991–9.
39 Biringer E, Tjoflåt M. Validation of the 24-item recovery assessment scale-revised (RAS-R) in the Norwegian language and context: a multi-centre study. *Health Qual Life Outcomes* 2018;16:23.
40 Kessler RC, Andrews G, Colpe LJ, *et al*. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. *Psychol Med* 2002;32:959–76.
41 Loh A, Simon D, Wills CE, *et al*. The effects of a shared decision-making intervention in primary care of depression: a cluster-randomized controlled trial. *Patient Educ Couns* 2007;67:324–32.
42 De Wilde EF, Hendriks VM. The client satisfaction questionnaire: psychometric properties in a Dutch addict population. *Eur Addict Res* 2005;11:157–62.
43 Rettke H, Lehmann AI, Brauchli R, *et al*. Capturing interprofessional collaboration between physicians and nurses in an acute care setting. A validation study of the revised German version of the Collaborative practice scales. *J Interprof Care* 2020;34:211–7.
44 Kriston L, Scholl I, Hölzel L, *et al*. The 9-item shared decision making questionnaire (SDM-Q-9). development and psychometric properties in a primary care sample. *Patient Educ Couns* 2010;80:94–9.
45 Murdoch J. Process evaluation for complex interventions in health services research: analysing context, text trajectories and disruptions. *BMC Health Serv Res* 2016;16:407.
46 Anon. Declaration of Helsinki (1964). *BMJ* 1996;313:1448–9.
47 The General Data Protection Regulations (GDPR). *The general data protection regulations (GDPR). Regulation (EU) 2016/679*, 2016.

SDU

Consent to processing of personal data

In connection with project Development of a Shared Care Model, SDU wants to collect information about people. SDU is responsible for the protection of personal data collected for the use in research projects. Participation in the project in voluntary. Collection takes place via visits in Psychiatric outpatient clinics in Denmark.

Purpose of processing information for the project
We want to investigate what people with mental illness and health professionals find important in the treatment process, as well as to elicit their perspectives on shared care, collaboration, and recovery.

How we use the information
The information is to be processed in accordance with the General Data Protection Regulation (GDPR) art. 6, (1)(a) and art. 9, (2)(a) which are about the rules of consent. SDU will treat the information with confidentiality in accordance with applicable law. We will make sure to keep the data secure so that only relevant researchers at SDU will have access to them. The information will only be used for research purposes.

Deletion and storage of your data
SDU will delete or anonymise the information when it is no longer relevant to keep. This will most often be when the project is completed, but it may also be later for the sake of possible documentation of the research results. The information will be deleted at the latest five years after the end of the project and will therefore be deleted on December 2028. You may withdraw your consent if you wish to have your data deleted earlier.

Please note

- that you can always withdraw your consent, which means the SDU is obligated to delete the information we have collected about you,
- that you have the right to see the data we have about you,
- that you have the right to request the rectification or deletion of data and
- that you have the right to appeal to the Danish Data Protection Agency about the processing of the information via www.datatilsynet.dk.

You always have the option of withdrawing your consent by writing to mhmarcussen@health.sdu.dk.

Publication
There will be no publication of data within which you can be identified. Your personal data is anonymised before being included in the publication of the results of the research. This means that it is not possible to retrieve your information within any publications.

More information
If you have any questions about the research, you can contact Michael Marcussen at any time. +45 26369503 or mhmarcussen@health.sdu.dk.

If you have any questions regarding data protection or your rights, you can contact our Data Protection Officer, Simon Kamber, by calling +45 65 50 39 06 or sending an email to dpo@sdu.dk.

If you wish to file a complaint about the processing of personal data, you can contact the Danish Data Protection Agency via www.datatilsynet.dk.

Declaration of consent

☐ I understand that participation in the project is voluntary.

☐ I understand that information about me will only be used for research.

Date Name Signature