FÆLLES ANSØGNINGSSKEMA
TIL KVALITETS- OG UDVIKLINGSMIDLERNE UNDER
KEU

REGION: Region Midtjylland	DATO: 13/4 2018	LØBENR.: (udfyldes af regionen)

STAMOPLYSNINGER

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PROJEKTBESKRIVELSE

PROJEKTETS TITEL: The Phy Psy Trial (PPT)

PROJEKTETS (ANSØGNINGENS) EMNE:
Behandling af fysisk sygdom hos patienter med svær psykisk sygdom (SMI).

OPDATERING VEDR. TIDLIGERE AFHOLDT PROJEKT (sæt x):

NYOPRETTET PROJEKT (sæt x): x

FORMÅL:

Phy Psy projektets overordnede formål er at reducere sygelighed for SMI patienter gennem en ny optimeret og koordineret behandlingsmodel med udgangspunkt i almen praksis.
I første fase af Phy Psy studiet er formålet at undersøge forskellige brugerbehov gennem en struktureret udviklingsproces med afsæt i nyere metoder til samskabelse og Co-design. Målet er at udvikle en robust og bæredygtig model med udgangspunkt i den eksisterende sundhedsorganisation og tilpasset en dansk almen praksis kontekst.
Vi sørger delvis finansiering til gennemførelse af den første fase ved KEU.

PROJEKTBESKRIVELSE (kort resumé) – selve projektbeskrivelsen vedlægges som bilag, der kan linkes til.

Mennesker med svær psykisk sygdom dør 10-20 år tidligere end mennesker uden svær psykisk sygdom. En væsentlig grund hertil er underdiagnostisering og underbehandling af fysiske sygdomme. Ofte behandles disse patienter på tværs af sektorgrænser, hvorfor koordineret behandling på tværs af almen praksis, kommuner og hospitalspsykiatrien er afgørende. Forskellige integrated care modeller, designet uden for almen praksis, er de senere år blevet testet – også i en dansk kontekst - men med skuffende resultater, hvad angår engagement og deltagelse hos både patienter og almen praksis.

Phy Psy studiet ønsker derfor at udvikle en ny model til håndtering af fysisk sygdom hos svært psykisk syge, der tager udgangspunkt i patienterne og en dansk almen praksis kontekst

Med en brugerinddragende Co-design tilgang ønsker Phy Psy-studiet at udvikle en behandlingsmodel til opsporing og behandling af fysisk sygdom hos SMI patienter, der tager afsæt i konkrete behov og giver mening for brugerne af indsatsen. Patienters, lægers og andre interessenters erfaringer, præferencer og perspektiver vil derfor blive afdækket gennem etnografiske metoder – herunder observationsstudier og interviews. Læger og personale fra almen praksis og øvrige interessenter inddrages i det konkrete udviklingsarbejde i samskabende workshops. Interventionen skal pilottestes i almen praksis og siden afprøves i et randomiseret kontrolleret forsøg.

Phy Psy studiet foregår i Region Midtjylland og Region Sjælland og drives i et tæt samarbejde mellem forskellige forskningsmiljøer – herunder Forskningsenheden for almen praksis i København, der er overordnet ejer af projektet, ved Susanne Reventlow.

Forskningsenheden for almen praksis i Aarhus bidrager til udviklingen af interventionen gennem kvalitative, eksplorative studier, samt leder brugerinddragelsesprocesserne (fokusgrupper, interviews og workshops) i Region Midtjylland, og er desuden ansvarlige for design og gennemførelse af pilottestning af den udviklede intervention.

EVALUERING (metode og tidsramme samt plan for implementering og formidling) ***(1)***

Metode

I forbindelse med den indledende behovsafdækning og Co-design fase involveres praktiserende læger, praksispersonale, behandlere fra psykiatri og udvalgte kommuner i Region Midtjylland i kvalitative studier og workshops med henblik på samskabelse af en bæredygtig intervention med afsæt i en almen praksis kontekst. Almen praksis inviteres via opslag på praksis.dk. Ansøgningen til KEU vedrører altså udviklingsfasen af Phy Psy behandlings- og samarbejdsmodellen. Vi har i første kvartal afholdt indledende opstartsmøder og interviews med alle interessenter og har fået stor opbakning og løfte om deltagelse i projektet fra alle. Selve udviklingsfasen er planlagt til at forløbe fra medio 2018 til udgangen af 2019.

Tidsplan:

Dataindsamling og Co-designprocesser overlapper og integreres i en toårig udviklingsfase.

<u>Modeludvikling gennem Co-design processer:</u>

- 2 indledende fokusgrupper (én med deltagelse på tværs af sektorer og fagdiscipliner, én udelukkende med deltagelse af praktiserende læger)
- Individuelle interviews med praktiserende læger (ca. 4) à ca. 1 times varighed
- Workshop 1 (5 timer): Tværsektorielt og tværdisciplinært med **fokus på samarbejde**

omkring og behandling af fysisk sygdom hos patienter med svær psykisk sygdom. Konkret bud på ny model udvikles gennem veltilrettelagt proces med henblik på pilottest i udvalgte praksis. Deltagerantal: Ca. 25 (heraf 4 praktiserende læger og 4 praksispersonaler)

- Workshop 2 (3 timer): Praktiserende læger og praksispersonale udvikler **praksismodel** inklusiv elementer til identificering, indkaldelse, undersøgelse, behandling og opfølgning. Deltagerne udvikler konkret forslag til afprøvning i pilottest. Deltagerantal: Ca. 16 (heraf 8 læger)
- Pilottest af prototype af interventionen udviklet på workshop 1 og 2.
- Workshop 3 (5 timer): Videreudvikling/**tilpasning af modellen** på baggrund af resultater fra pilottest. I tværsektorielt og tværdisciplinært set-up udvikles bud på den "endelige" intervention. Deltagerantal: Ca. 25 (heraf 4 praktiserende læger og 4 praksispersonaler)

Dataindsamling

- Observation mhp læring om hvordan tværsektorielle interventioner bedst udvikles
- Kvalitative studier (observation og interview) og kvantitative studier (registrering af patientforløb) i forbindelse med pilottest

Outcome:
Resultater skal anvendes dels i udviklingen af en prototype for optimeret behandling af fysisk sygdom hos SMI patienter, dels i pilottesten af prototypen, samt feasibility studie, der vil gå forud for en større afprøvning (RCT) af den endelige intervention (se mere om den endelige intervention i den vedhæftede projektbeskrivelse).

Triple Aim:
Der er i det overordnede Phy Psy projekt indarbejdet arbejdspakker, der skal sikre, at der i forbindelse med afprøvning af den udviklede intervention gennemføres en sundhedsøkonomisk evaluering, ligesom der indgår følgeforskning med inddragelse af den oplevede kvalitet hos brugerne af interventionen. Ligeledes vil der blive målt på patienternes sundhedsmæssige outcome, samt patienternes selvrapporterede outcome (PROM). I denne del af projektet er fokus på inddragelse af almen praksis og øvrige sundhedsprofessionelle i selve udviklingen, samt den oplevede kvalitet af interventionen i forbindelse med pilottesten.

Formidling:
Resultater fra Co-design fasen (udviklingen af Phy Psy interventionen) vil afrapporteres i form af videnskabelige artikler og evalueringsrapport.

Tidsramme
2018:

- Opstartsmøder med centrale stakeholders (almen praksis, region, psykiatri, kommuner)
- Rekruttering af deltagere fra almen praksis (herunder udvikling af informationsmateriale og invitationer)
- Indledende behovsafdækning (fokusgrupper, individuelle interviews)
- Analyse af data fra indledende behovsafdækning
- Planlægning og afholdelse af Workshop 1 (herunder udvikling af indhold og materiale, booking af lokation og forplejning)
- Afrapportering af foreløbige resultater til overordnet Phy Psy forskergruppe. Yderligere kvalificering.
- Planlægning og afholdelse af Workshop 2 (udvikling af almen praksis elementer) (herunder udvikling af indhold og materiale, booking af lokation og forplejning).
- Løbende analyse af co-design aktiviteter

2019:

- Pilottest af prototype (inkl. udvikling af implementerings- og evalueringsstrategi, rekruttering af almen praksis til pilottest) – varighed 3-4 uger.
- Dataindsamling i forbindelse med pilottest (Observationsstudier + Individuelle interviews)
- Planlægning og afholdelse af workshop 3 (udvikling af "endelig" intervention)
- Formidling af resultater fra co-design aktiviteter (artikel)

2020:

- Feasibility studie af "endelig" intervention (udvikling af studiedesign, rekruttering af praksis, kvalitative studier, analyse og formidling)

Milepæle:

Milepæl 1: 01.10.18 observationsstudier og fokusgruppeinterviews er bearbejdet og temaer omkring brændpunkter, som udfordrer behandling af målgruppen i almen praksis er klarlagt.

Milepæl 2: 01.02.19. Arbejdet i workshops 1 og 2 har affødt udvikling af behandlingsmoduler, der indeholder guidelines til organisering af arbejdet med målgruppen, en model for opretholdelse af kontakt mellem patient og almen praksis; en model for samarbejde med hospitalspsykiatri, sagsbehandler, og socialpsykiatri.

Milepæl 3: 01.06.19. Pilotaftest af behandlingsmoduler og øvrige modelelementer indikerer modenhed til implementering i RCT.

Milepæl 4: 31.12.19. Tilpasset Phy Psy model på baggrund af erfaringer fra pilottest og workshop 3, samt feasibility studie.

(RCT følger fra 2020-2025).

Vurdering/overvejelse om efterfølgende udbredelse og implementering i almen praksis

I udviklingen af en ny model, til hvordan vi forbedrer behandlingen af denne patientgruppe, har vi som udgangspunkt en ambition om, at modellen skal resultere i mærkbare forbedringer for patienterne. Men den skal også være realistisk og mulig at indføre i det daglige kliniske arbejde. Derfor skal den i udgangspunktet opleves som meningsfuld og givende for almen praksis, der er den centrale spiller i interventionen, og virke uden at det forudsætter systemændringer, der ikke er realistiske. Perspektivet er således, at modellen, hvis den fungerer godt, umiddelbart overgår fra projekt til drift, og derfor skal de involverede parter også være deltagende under udvikling og afprøvning af modellen.

Erfaringen, vi får med modeludviklingen, som vi søger midler til, vil også bidrage med mere generel læring om, hvordan tværsektorielle samarbejde bedst kan udvikles, hvilket vil være nyttig ved fremtidige lignende projekter i Regionen

START- OG SLUTTIDSPUNKT (evt. forventet): 2018-2019 (udviklingsfasen hvortil KEU midler søges)

BUDGET

ANSØGT BELØB: 568.077 kr. (Et udspecificeret budget er vedlagt, hvor det er markeret præcist hvilke midler, der ansøges om hos KEU)

Lønmidler til projektleder
Der ansøges om midler til finansiering af projektleder i forbindelse med planlægning af fokusgrupper og workshops, rekruttering af deltagende praktiserende læger og praksispersonale, samt planlægning og facilitering af workshops.

Afholdelse af workshops og interview:
For at sikre motivation og engagement afholdes mødeaktiviteter eksternt og med forplejning (se vedlagte budget).

Honorering af almen praksis:
Der ansøges om midler til honorering af praktiserende læger i Region Midtjylland for deltagelse i fokusgrupper og workshops, samt til almen praksis' deltagelse i pilottest af interventionsprototype. Der betales, i forbindelse med fokusgrupper og workshops, konsulent timetakst på 918,54 kr. til deltagende praktiserende læger. Frikøb af praksispersonale med en timetakst på 290 kr. (oplyst ved Dansk Sygeplejeråd) dækkes ved egen finansiering.

Indledende fokusgrupper:

- Fokusgruppe 1 (tværsektoriel): 3 praktiserende læger (+ 3 praksis personale) i 1,5 timer
- Fokusgruppe 2 (almen praksis alene): 8 praktiserende læger (+ 8 praksispersonale) i 1,5 time

Indledende interviews med praktiserende læger:

- Individuelle interviews: 4 læger à 1 times varighed = 4 timer

Workshops**:**

- workshop 1: 4 læger (+ 4 praksispersonale egenfinansieret) i 5 timer = 20 timer
- workshop 2: 8 læger (+ 8 praksispersonale egenfinansiering) i 3 timer = 24 timer
- workshop 3: 4 læger (+ 4 praksispersonale) i 5 timer = 20 timer

Pilottest:

- Individuelle interview: 6 praktiserende læger i 1 time = 6 timer

Transportgodtgørelse:

- For 37 deltagende praktiserende læger med en gennemsnitlig transport på 50 km a 3,54 kr./km.

BEVILLING (indeværende år og evt. efterfølgende år):

ANSØGT MIDLER SPONSERET FRA ANDRE SIDER:

PPT-projektet har modtaget en bevilling fra Novo Nordisk Fonden på 25 mio.kr. over en 5 årig periode. Bevillingen går til aflønning af videnskabeligt personale (se egenfinansiering i budget) og til udvikling af en IT infrastruktur, der kan understøtte projektaktiviteterne.

Der er ikke modtaget bevilling til aflønning af projektleder til koordinering, rekruttering, planlægning og facilitering af fokusgrupper og workshops, ligesom honorering af praktiserende læger for hjælp til indsamling af data heller ikke er finansieret.
BUDGET FORDELT PÅ ÅR: Se vedlagte udspecificerede budget. **2018**: 564.911 kr. **2019**: 674.511 kr.
TOTALBUDGET: 1.239.422 kr.

AFSLUTTENDE RAPPORT/ARTIKEL SENDES TIL DET REGIONALE SEKRETARIAT:
SUPPLERENDE OPLYSNINGER:
BILAGSFORTEGNELSE: Bilag 1: Overordnet projektbeskrivelse for Phy Psy projektet Bilag 2: Budget

A cluster randomised, parallel-group, 5-year trial of coordinated, co-produced care to reduce the excess mortality of patients with severe mental illness by improving the treatment of their comorbid physical conditions.
The Phy-Psy Trial

Copenhagen
September 2016

1) Introduction

a) The problem

People with severe mental illness (SMI) comprise about 2% of the Danish population and they die 10-20 years earlier than people without SMI [1]. In Region Zealand and Central Denmark Region, the 10-year mortality of patients aged 18-65 admitted to a psychiatric department during the preceding 5 years is 18.1%, while it is 4.3% in the rest of the population (own unpublished analysis). Most of this excess mortality stems from physical diseases [2], which are underdiagnosed and undertreated [3]. These patients are treated across sector borders and coordinated care between general practice, municipalities and hospital psychiatry is considered imperative. Different initiatives using integrated care models designed outside general practice have been tested but with disappointing results and with difficulties in engaging both patients and general practice [4].

b) Strengths of the consortium

This project brings together a unique partnership of institutions with a long-term dedication to general practice research. The project is initiated by and rooted in the Center for Research and Education in General Practice, University of Copenhagen (CFUAM), and involves a multidisciplinary team of leading academic experts within general practice, psychiatry, clinical pharmacology, clinical trials, co-design, health economics, organisational research, and computer science. The commitment of a broad range of organisational partners with reference to all the stakeholders involved consolidates the implementation of the intervention.

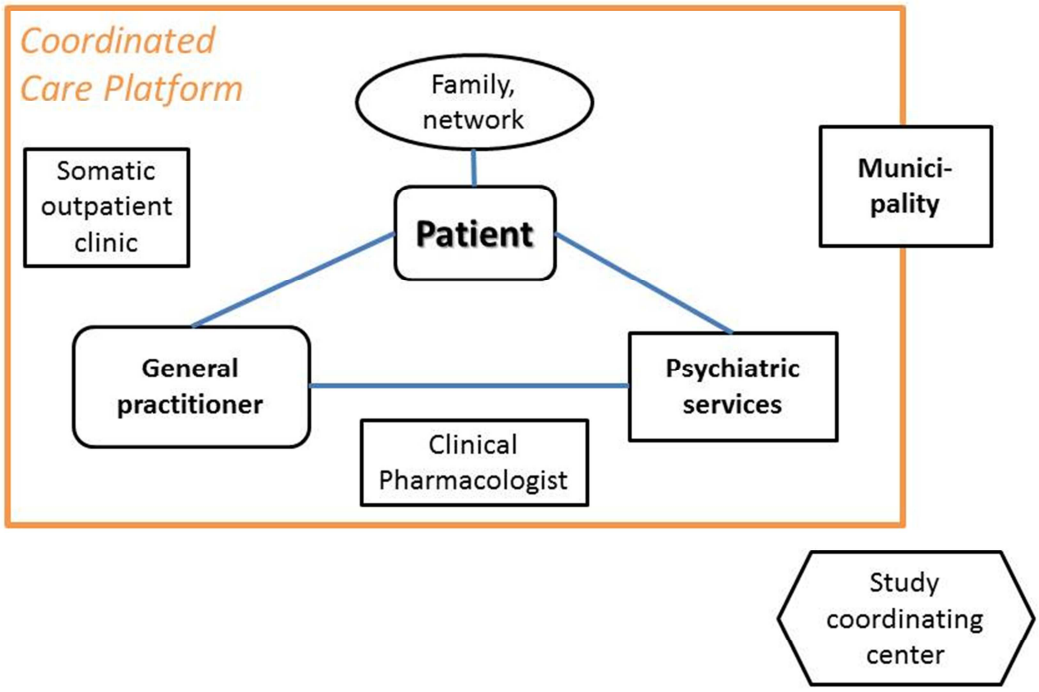
2) Over-all idea and ambition

This study will develop, execute, and rigorously test in a randomised controlled trial (RCT) an intervention consisting of a coordinated care plan supported by an integrated information and communication technology (ICT) care platform. The aim is to reduce all-cause mortality in people with SMI. This care model targets challenges with insufficient care in this vulnerable group, in particular underdiagnosis and undertreatment of comorbid physical conditions. The intervention will be developed by combining state-of-the-art evidence-based clinical, social and technological knowledge with the perspectives of all involved parties in a participatory co-design process (Figure 1). During a preparatory design phase barriers and facilitators for a successful coordinated care plan involving all stakeholders will be identified.

3) Innovation potential

The envisaged intervention has the potential to develop an effective care model, integrating clinical work, organisational aspects, technology and communication leading to longer life, better health and better quality of life for people with SMI. The intervention will optimise utilisation of existing resources supported by an ICT care platform, and strengthen cross-sectorial coordination and interpersonal relations.

Figure 1. The stakeholders



4) Relation to NNF call

The vision of a coherent healthcare system is challenged to its limits by patients with SMI. This study intends to develop and implement a clinically effective coordinated care model for these vulnerable patients allowing for individualised treatment focusing on their often multiple physical conditions. Both the professional stakeholders, like general practice, psychiatric departments, and municipalities, and the patients' families and networks will be involved in effective collaboration and communication supported by technological solutions. The new created knowledge will be generalisable to other vulnerable patient groups with multiple chronic conditions and complex social and health problems.

5) Concepts and approach

a) Positioning of project

In order to be implemented in general practice, municipalities and hospital psychiatry, a cross-sectorial care model must make sense for all involved professionals. General practice has responsibility for the continued and longitudinal care of all patients' diseases. The approach is patient-centred and often includes collaboration with the families. Consequently, general practice is the natural candidate for taking on a proactive and coordinating role in a coherent care model involving relevant institutions in a mutually committing and competent collaboration (Figure 1). Such a model will ensure optimal care pathways for patients with SMI at the lowest effective level of care and enable effective communication between the sectors.

b) Relation to previous research

The high prevalence of physical comorbidities in patients with SMI is partly explained by sedentary lifestyle, unhealthy diet, and poor quality of healthcare [5]. However, targeting lifestyle

changes to improve the physical health of people with SMI has failed to demonstrate substantial benefits [4]. Underdiagnosis of cardiovascular disease and underprescription of cardiovascular drugs to SMI patients are well documented [1]. A post hoc analysis of the randomised trial Diabetes Care in General Practice (DCGP) suggests that structured, individualised diabetes care in general practice markedly reduces mortality among patients with diabetes and SMI [6]. Patients with SMI often receive (poly)psychopharmacological therapy in addition to treatment for their physical conditions. In Denmark, preliminary unpublished results from studies to optimise polypharmacological treatment show that guidance from clinical pharmacologists or pharmacists is most effective when it is shared with the clinician in charge of the patient's care in a person-to-person contact.

For patients with SMI the diversity of the comorbid diseases, patients' limited personal resources and often severe social challenges increase the complexity [7]. A novel set of interventions, tailored to the needs, preferences, and values of patients with SMI and applicable to the existing healthcare system [8] is warranted to make better use of available resources through improved coordination and cooperation between all three sectors [9]. Models of integrated care designed to overcome the challenges of an increasingly fragmented health and social care system have shown disappointing results, partly because they were not able to secure commitment from general practice [4 10]. These studies have pinpointed important preconditions for effective coordinated care: 1) careful preparation, 2) qualitative process evaluation as an integrated part of the overall study, and 3) involvement of all stakeholders from beginning to end. Research evidence suggests that SMI patients with support from informal carers can achieve better outcomes, including fewer hospital admissions and relapses, better engagement with treatment, and improved mortality rates. Carers play a central role in the care and support for SMI patients at initial onset, and in responding to incipient signs of relapse and unmet needs [11].

Finding a balance between the patient's 'capacity' (i.e. time, resources, and health literacy) and the 'workload' associated with care is essential [12] and may be strengthened by a patient-centred approach enhancing patient involvement [13]. ICT can provide a care platform for coordination, communication, and execution of activities across multi-disciplinary care teams. Personal health technologies can increase the involvement of patients and their networks and enable self-reporting on core parameters [14]. This data can be used to identify important aspects of patients' health status and patterns of health behaviour enabling prediction of disease progression.

c) Overall approach and methodology

1. Understanding user perspectives

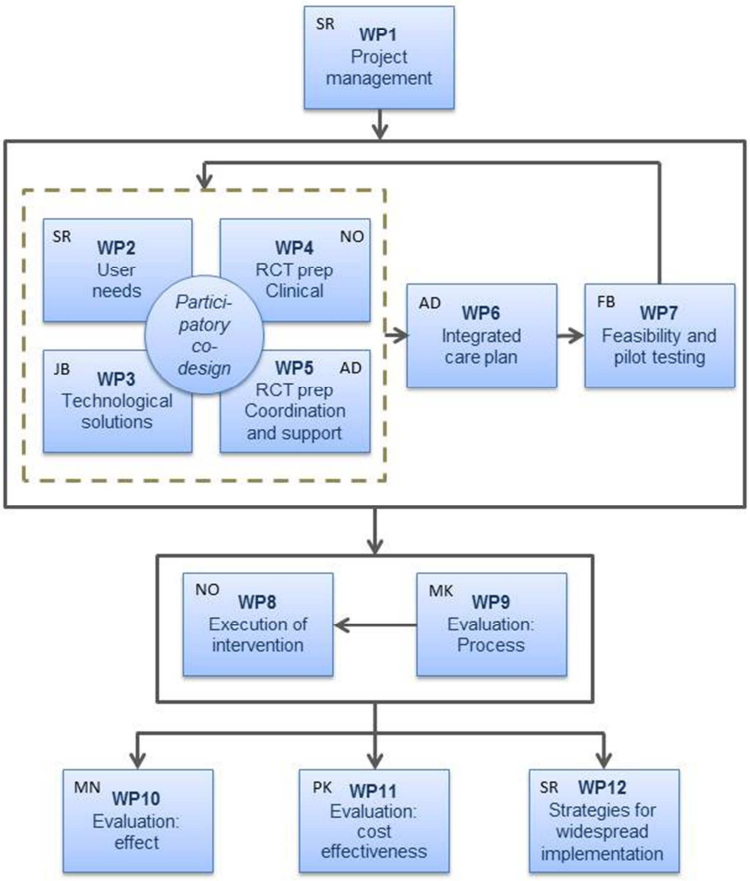
To develop a coordinated care plan that will be effective and can engage patients, general practice, and other stakeholders, experiences, needs, preferences, and values of these users will be explored. This will be done by ethnographically inspired methods including interviews with and observations of patients, their families, and relevant professionals. The results will assist in establishing adequate strategies for coordinated care which are sensitive to situational and cultural context, involve patients and their families and networks, and build on cooperation between health and social professionals [15]

2. Participatory co-design

A participatory co-design will build on the study of user perspectives and encourage collaborative work on health care system design [15]. By co-designing the intervention all stakeholders can take ownership of the care model, thereby promoting its implementation. Participatory co-design will be conducted through iteration of explorative studies in Work Package (WP) 2-5 (Figure 2) followed by joint workshops involving all stakeholders (Figure 1). Interactive methods will be applied to create reflection on the different elements of the intervention, e.g. care plan, communication, collaboration, and ICT. These methods will also

enable addressing potential unintended consequences during the design phase. Data will consist of observations and written material that will be analysed thematically [16]. The results will drive the development of the final intervention model, including the supporting ICT care platform.

Figure 2. Work package structure



3. The intervention

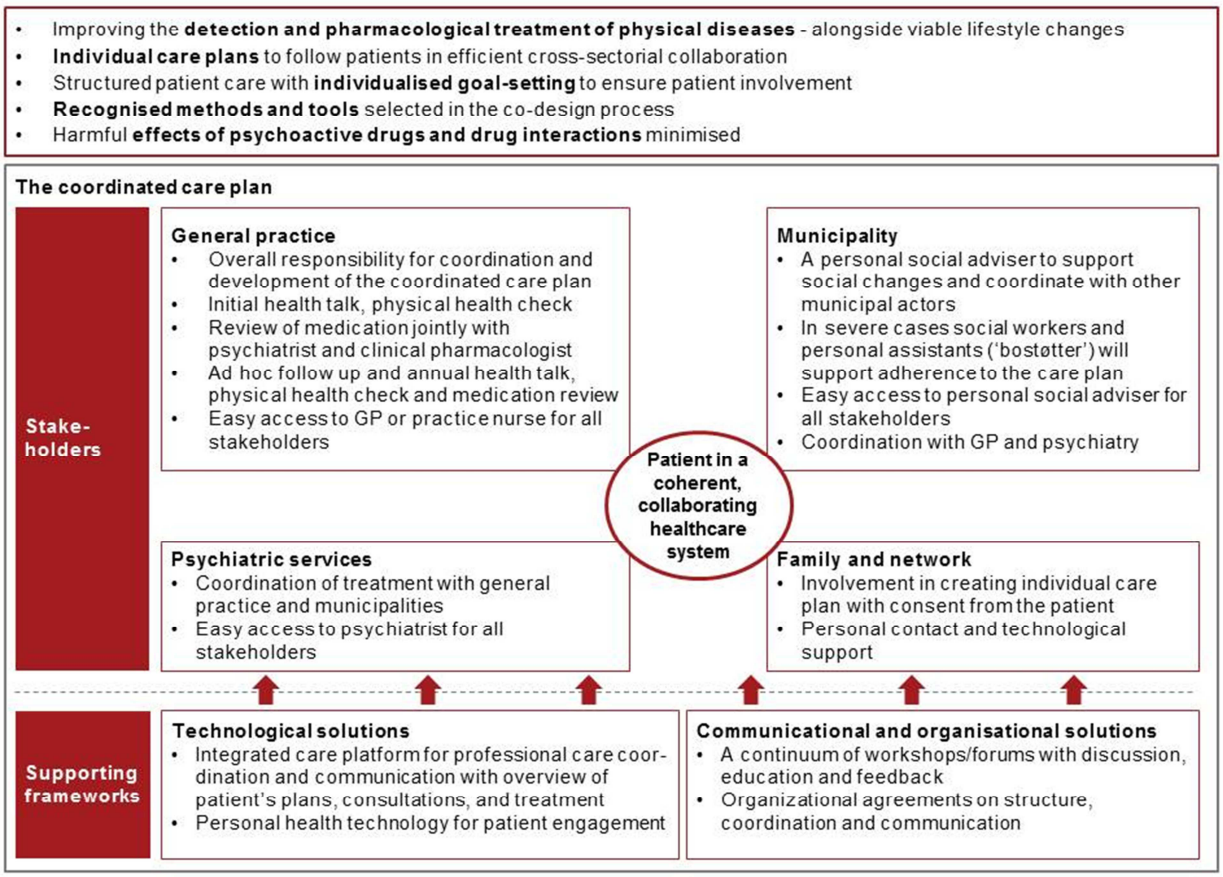
The main focus of the proposed complex intervention will be on improving the detection and pharmacological treatment of physical diseases in patients with SMI through a mutually committed and efficient cross-sectorial collaboration in a team of named people in the cooperating sectors and with agreement about contacts, and forms of communication (Figure 3). The team which includes clinical pharmacologists, social workers and psychiatrists will support the primary care professionals responsible for the sustained medical care of SMI patients. Alongside, viable lifestyle changes will be implemented. Harmful drug effects and interactions will be minimised through individualised advice from the clinical pharmacologist. A general practice nurse will be appointed to take responsibility for the coordinated care plan of the individual patients. Eligible patients will be contacted from general practice and invited to participate. An individual treatment plan with realistic and individual goal-setting to engage

patients in their treatment, will be worked out for each patient and approved by all stakeholders [6]. Further consolidation of the individual care plan is sought by involving the patient's family and network. The plan will follow the patient across sector borders, and the ICT care platform will provide up-to-date information flow between all stakeholders. Throughout the intervention period regular teaching sessions for patients and professionals and cross-sectorial workshops will be conducted to support the implementation and sustainability of the coordinated care model.

4. Technological solutions

An ICT care platform will be developed to support two fundamental purposes: 1) effective communication and collaboration between all stakeholders and 2) strengthening patients' participation and adherence to effective treatment of comorbid physical diseases (Figure 3). The work with the first purpose will be based on prior research in computer supported cooperative work (CSCW) for healthcare coordination [17]. For the second purpose the approach of Personal Health Technology [14] will be applied to develop a patient platform as a basis for patient involvement and to provide essential data streams for disease monitoring, analysis, and prediction. In combination, 1) and 2) will provide an ICT care platform which actively engages both the professional care team and the patient in monitoring and treatment of diseases. This allows for early intervention based on triggers and warning signs enabling a proactive care model based on shared decision-making.

Figure 3. Elements of the coordinated care plan



5. Evidence base

The coordinated care intervention will be developed in WP2-6 and pilot-tested in several iterations in WP7 (Figure 2). This process will be meticulously informed by user needs and requirements, theories of behaviour change, audits, workshops, technological research and innovation, and previous and on-going research by the consortium and other researchers. All stakeholders will be involved in this experience-based co-design process.

6. Patient population

The intervention will take place in Region Zealand and Central Denmark Region. All the psychiatric centres are expected to participate in the study. Inclusion criteria: 1) group 1-insured; 2) age 18-65 years; and 3) hospitalised at a psychiatric department within five years prior to study start. Exclusion criteria: 1) life-threatening disease; 2) consent declined; 3) inability to understand and speak Danish; and 4) concerns about participant or staff safety.

7. Power calculation

It is expected that 80% of the municipalities will participate and within each municipality 50% of general practices, which is a maximum of 259 participating practices. In each practice there is a mean of 25 SMI patients, aged 18-65 years, of which 60%, i.e.15, are expected to participate. Measured from year 2000 in the two participating regions, the 5-year mortality in the SMI group was 9.2%. To be able to detect a reduction of 5-year mortality to 67%, as observed in the DCGP study [6], with 80% power, 200 practices are needed. This figure is conservative, as a high interclass correlation coefficient of 0.2 is assumed to account for SMI patients being more similar within a single practice than between practices.

8. Randomisation and blinding

The randomisation unit is general practice postal address. 1:1 randomisation is done, independently of the study coordinating centre, with a computerised randomisation sequence stratified according to municipality. The study is open, but outcome assessment will be blinded.

9. Evaluation

The evaluation of the complex intervention will employ quantitative and qualitative methods to cover different key dimensions [18]:

a) Evaluation of effectiveness (WP10)
The outcomes assessed in the randomised trial are:
1. Primary outcomes: The 5-year all-cause mortality. Data source: The Danish Civil Registration System.
2. Secondary outcomes: 5-year cardiovascular mortality and morbidity. Data sources: The Danish Register of Causes of Death and the Danish National Patient Register. The choice of other secondary outcomes will be decided during the preparation phase, e.g. quality of life, self-rated health, hospital admission, use of medication, suicidal behaviour. Supplementary explorative outcomes could be patient reported outcome measures (PROMs) related to function, work, treatment burden, continuity of care and involvement. The quantitative outcomes will be analysed according to the intention-to-treat principle with Cox proportional hazard regression models taking clustering into account.

b) Process evaluation of intervention delivery, change mechanisms, user experiences and organisational prerequisites for implementation (WP9).
An extensive process evaluation of the intervention will be conducted [19] examining a) intervention delivery and adoption by participating organisations and professionals; b) users' (professionals, patients, and relatives) experiences and assessments of the intervention including the ICT care platform, and c) important mechanisms of change. Normalization Process Theory will be used to analyse the barriers and facilitators of the implementation [20].

Organisational structures affecting adoption and outcomes of the intervention will be evaluated to assess options for more widespread implementation.

c) Cost effectiveness evaluation (WP11)
The evaluation of cost-effectiveness will compare the costs and health outcomes of the intervention. This will include an analysis of utilisation patterns of secondary somatic and psychiatric care as well as primary care for the follow-up period. Confidence intervals for estimates of cost-effectiveness will be estimated using bootstrapping methods.

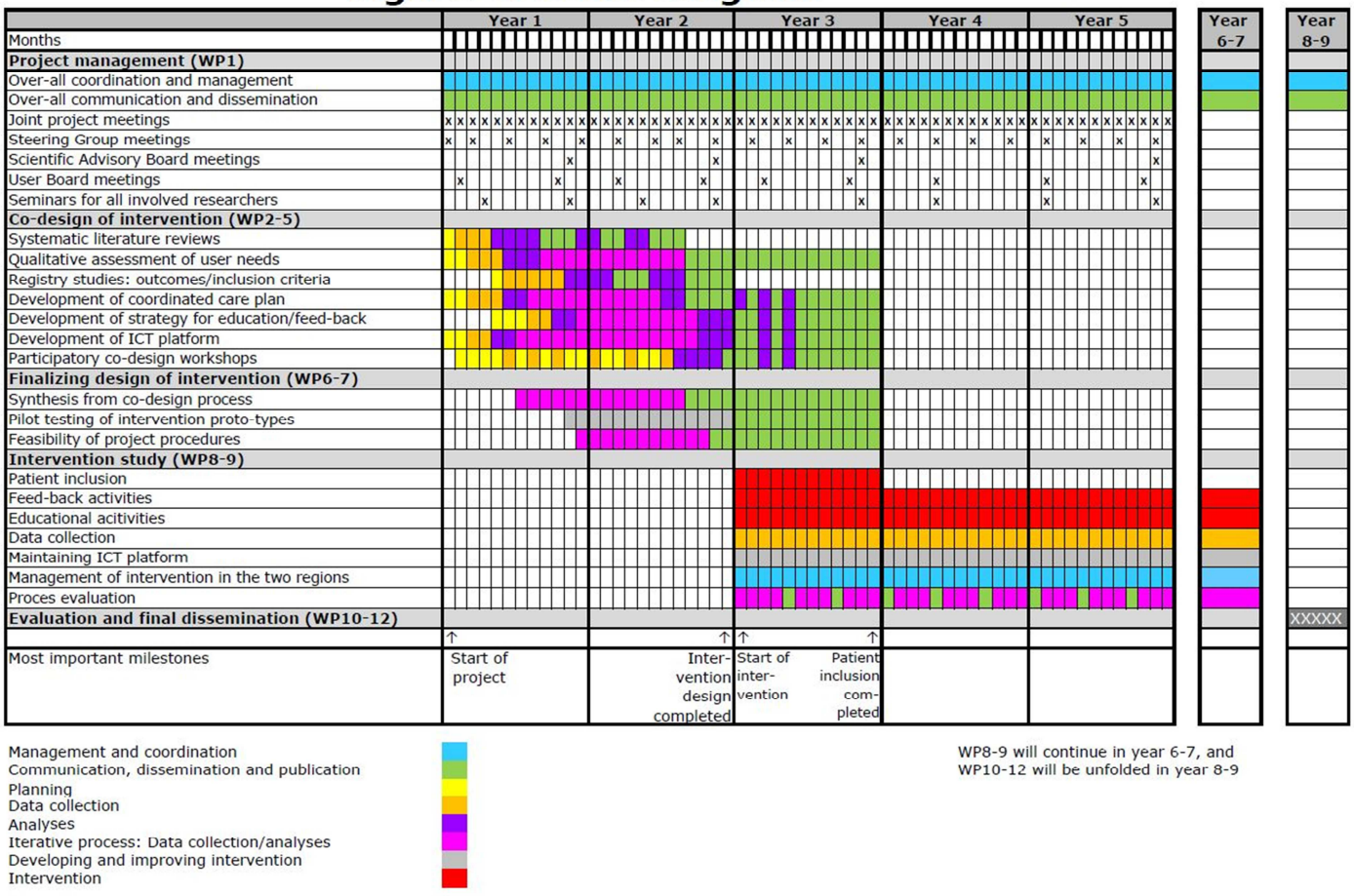
10. Gender issues

A previous study has shown improved outcomes in women receiving structured individualised diabetes care [21] although no gender difference was found in previous Danish integrated care studies [4]. This study will apply a gender perspective to rethink the way medical care is provided for both men and women.

11. Timeline and financial support

The preparatory phase of the study is scheduled to last 2 years followed by 5 years of intervention and process evaluation (Figure 4). After the termination of the intervention a 2-year phase will follow with evaluation of effect and cost-effectiveness, dissemination and implementation. During the first 5 years of the study the consortium will apply for additional funding to support year 6-9.

Figure 4. Gantt Diagram



6) Impact

a) Expected impacts

It is expected that

1. The care model will reduce patients' excess mortality, improve function, and PROMs [6].

2. The intervention will foster collaboration and coordination between sectors and lead to more effective treatment at the lowest effective level of care.

3. The thoroughly developed coordinated care model will promote continuity of care in general practice and coherent treatment across sector borders.

4. The co-designed approach will ensure involvement of patients, their families, and relevant stakeholders ensuring engagement and sustainability of the model.

5. An effective collaborating care model for patients with SMI can be transferable to other vulnerable patient groups.

b) Communication and dissemination measures

By developing a complex intervention and testing it in an RCT, high quality evidence on the efficiency of the intervention will be produced. Using the co-design model all stakeholders will be involved from a very early stage of the project and thereby create a close and long-lasting collaboration that will enable effective dissemination of the results and experiences. To maximise the impact, the results will be disseminated to patient and caregiver organisations, municipalities, regional and national politicians, the general population, general practitioners, psychiatrists, pharmacists, pharmacologists, and other researchers. Approximately 30 scientific papers will be published in international peer-reviewed journals on specific results from the WPs. In addition several joint papers on overarching methodological aspects will be produced.

7) Implementation

a) Work packages (Figure 2)

1. WP1. Project management

Management will be efficient and secure a consistently high quality of research at all stages. WP1 deals with the administrative, financial, legal, data protection, and ethical management of the project and is also responsible for the overall management and coordination within and between work packages. A Project Manager will be appointed and will have daily responsibility for coordination and working relationships with the work package leaders, including running the Steering Group, Scientific Advisory Board and User Board.

2. WP2. User perspectives/Co-design

To ensure a detailed understanding of current practices, needs, and challenges in daily management of patients with SMI and form the basis for development of the intervention, WP2 will 1) explore the experiences, needs, preferences, and values of patients, their relatives, networks, and the professionals who support them; and 2) identify desired outcomes and potential barriers for implementation of the intervention. Data will be produced by ethnographic methods including interviews with patients (15-18) and their networks (15-25), and 3-4 focus groups with health professionals across the sectors. The results of systematic qualitative analyses will be integrated in the co-design approach [16].

3. WP3. Technological solutions

Applying a participatory user-centred design process, WP3 will design the ICT care platform for coordinated care that combines a data-driven coordination platform with personal health

technology for patient engagement. WP3 will exploit the consortium's prior research in computer supported cooperative work (CSCW) for healthcare and personal health technology for mental health [14]. Focus will be on 1) user-friendly systems; 2) coordination support amongst the different stakeholders; and 3) a data-driven decision support setup.

4. WP4. RCT preparation – clinical

With input from WP2-3 and 5-7 the full trial protocol will be developed according to CONSORT guidelines [22 23] and approved by regulatory authorities. The choice of both patient selection criteria and clinical secondary outcomes will be qualified by register analyses and clinical audits in test practices. The complex intervention is expected to include the elements shown in Fig. 3 at least. A proposed clinical component of the intervention will be based on comprehensive reviews of high-grade evidence. Standards will be set up for the systematic integration of results from WP2-7 into the final intervention. Detailed standard operational procedures complying with Good Clinical Practice (GCP) will be developed for e.g. management, monitoring, and outcome assessment.

5. WP5. RCT preparation – coordination and support

Based on the findings from other studies and from WP2-3 [7 18] detailed models will be developed for: 1) role and duties of the coordinating practice nurse; 2) meeting forms facilitating cross-sectorial cooperation between all three sectors; 3) access to primary care; 4) allocation of social support to patients and their networks to facilitate adherence to the coordinated care plan; 5) coordination with psychiatry to improve mutual communication, coordination of overall care, and adjustment of medication; 6) instructions for use of the ICT care platform. The structure and content of consultations in primary care [24] and the meetings with the patients in the municipality will be adapted to ensure inclusion of patients' perspectives, preferences, and values, and adherence to treatment.

6. WP6. Coordinated care plan

A detailed coordinated care plan involving evidence based treatments for patients' comorbid physical conditions in a patient-centred approach will be developed and supported by the ICT care platform. The aim of the coordinated care plan is to 1) support patients pursuing their individual care plans and 2) ensure coordination, effective communication and mutual commitment between sectors. The individual care plans will include individualised guidance, goal-setting, and facilitate coordination across sector borders and with patients' network. A primary care practice nurse will have primary responsibility for coordination. Social support from the municipality and coordination with psychiatric services and the rest of the secondary health care sector will be secured. The knowledge partnership between stakeholders will be consolidated through educational methods, such as collaborative learning, experiential learning, feedback on individual patients, and e-learning.

7. WP7. Feasibility and pilot testing

As prototypes of the intervention are developed, including the ICT care platform, they will be tested in a few selected general practices and municipalities in several iterations. Issues of feasibility will include procedures for randomisation, recruitment, retention, clarification of sample sizes and outcome measures, and identification of potential barriers and facilitators to implementation (including the acceptability of the intervention for professionals and patients). In addition, the results from this WP will be used as inspiration when selecting specific areas of attention in the process evaluation.

8. WP8. Execution of intervention

The intervention will be carried out rigorously according to study protocol and execute educational and feed-back activities as well as individual care plans. GCP standards including monitoring trial implementation, and data quality will be applied. The monitoring system of selected indicators will continuously assess the delivery of the intervention and provide feedback to professionals and patients as well as input to prospectively design educational

activities that support project implementation. The ICT care platform will be hosted and operated at a hosting setup within the EU and in accordance with the data protection act.

9. WP9. Process evaluation

This WP will investigate the processes of delivery and adoption along with the various users' responses to the intervention [7]. Organisational factors will be explored to assess the potential for scalability and transferability. This will be based on qualitative data supplemented by clinical data from the trial. 6-8 general practices (variation in practice size and geographical location) will be followed throughout the intervention period. The different professionals (8-12 health/social care workers/ specialists from psychiatry respectively) will be interviewed 2-3 times supplemented by group interviews. Patients and relatives (10-15) will be interviewed about experiences during their trajectories.

10. WP10. Effect evaluation

The primary outcome will be assessed through national registries, while secondary outcomes will be assessed by a combination of national registries, study data collection, and stakeholder/patient reporting. Safety aspects and interim analyses will be presented to the Scientific Advisory Board. Intermediate clinical outcomes will be analysed to contribute to explaining the findings in predefined outcomes.

11. WP11. Evaluation of cost effectiveness

WP11 will supplement the evaluation of health outcomes, change processes, and user experiences by evaluating the cost-effectiveness of the intervention. The cost-effectiveness analysis will be performed on the basis of prospective collection of patient reported health related quality of life, costing of the intervention, and register analysis of health care utilisation.

12. WP12. Strategies for widespread implementation

This WP aims to maximise transfer and dissemination of the obtained knowledge to facilitate implementation. The partners will coordinate and plan scientific dissemination via peer reviewed journals and international conferences. Results will also be disseminated through dialogue and cooperation with patient organisations, GP organisations, municipalities, and health authorities. Basic information and publications from the project will be made available through a public website and social media to share ideas and results with key audiences. Workshops will be held to facilitate implementation of new coordinated care models.

b) Management structure and procedures

1. Overall management objectives

These are 1) to facilitate high quality research; 2) to coordinate activities across work packages; 3) to deliver on the administrative requirements; 4) to maximise the impact of the trial with a focus on dissemination and exploitation; and 5) to facilitate implementing the research results into guidelines and health policy.

2. Organisational structure

This trial is initiated by the University of Copenhagen, Aarhus University, and the Technical University of Denmark, in close collaboration with the Danish Institute for Local and Regional Government (KORA), regional psychiatric services, and municipalities. The project will be administered at CFUAM. The Steering Group (SR, NO, FB, JB, MN, PK, AD, MK, see below) will be supervised and assisted by the Scientific Advisory Board and the User Board. WP leadership is as in Figure 2. A Lead Project Manager and two Regional Project Managers will be appointed.

Lead applicant:

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Flemming Bro (FB), Aarhus University
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Merete Nordentoft (MN), Mental health services, University of Copenhagen

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Ann Dorrit Guassora (AG), CFUAM
Marius B. Kousgaard (MK), CFUAM
Volkert Siersma (VS), CFUAM

Collaborating partners:
Organisational partners
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PLO (Organisation of General Practitioners in Denmark)
DSAM (The Danish College of General Practitioners)
Department of Healthcare, Region Zealand
Department of Healthcare, Central Denmark Region
KL (Local Government Denmark). Contact: Tina Levysohn

Professional partners:
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John Brodersen, CFUAM and Region Zealand
Berit Kaae and Anna Mygind, The Copenhagen University General Practice Clinic and the research practices in Central Denmark Region
Søren Bredkjær and Per Jørgensen, psychiatric services in Region Zealand and Central Denmark Region
Mikkel Christensen, Clinical Pharmacological Department, Bispebjerg Hospital

Scientific Advisory Board:
Professor Stewart Mercer, Primary Care Research, University of Glasgow, Scotland
Professor Jane Gunn, Primary Care Research Unit, General Practice and Primary Health Care Academic Centre, University of Melbourne; Australia
Professor Sue Ziebland, Health Experiences Research Group, Department of Primary Health Care, University of Oxford, England
Professor Jürgen Unützer, Division of Integrated Care and Public Health, Department of Psychiatry and Behavioral Sciences, University of Washington, USA
Professor Anders Fink-Jensen, Psychiatric Centre Copenhagen and Department of Neuroscience and Pharmacology, University of Copenhagen, Denmark

8) Ethics

Approval will be applied for from the Danish Ethical Committee and the Danish Data Protection Agency. In addition, ethical issues will be a primary consideration at all levels of the study both when involving patients in a participatory design and during the RCT and the parallel qualitative process evaluation. Patients provide written informed consent on the basis of verbal and written information.

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Budget; The Phy Psy Trial -optimeret behandling af fysisk sygdom hos patienter med svær psykisk sygdom

	2018	2019	Egenfinansiering	Ansøges fra KEU	Total budget
Løn					
Forsker, Antropolog (4 mdr i 2018 og 6 mdr i 2019), 47.000 kr pr mdr	188.000	282.000	470.000		470.000
Projektleder (halv tid i 7 mdr i 2018 og halvtid i 12 mdr i 2019), 47.000 kr pr mdr (fuldtidsløn)[1]	168.000	288.000		456.000	456.000
Studentermedhjælp til transskribering (60 timer), 140 kr pr time,	8.400			8.400	8.400
Løn i alt	364.400	570.000	470.000	464.400	934.400
Drift					
Kontor plads, anskaffelser, sekretær, oversættelse, publikationsudgifter	30.000	45.000	75.000		75.000
Afholdelse af workshops (lokale, forplejning)					
Fokusgruppe interview 1	1.000			1.000	1.000
Fokusgruppe interview 2	1.000			1.000	1.000
Workshop 1 (forplejning praktiserende læger)	3.000			3.000	3.000
Workshop 2 (forplejning praktiserende læger)	6.000			6.000	6.000
Workshop 3 (forplejning praktiserende læger)		3.000		3.000	3.000
Drift i alt	41.000	48.000	75.000	14.000	89.000
Honorering og transport					
Honorering af praktiserende læger					-
Indledende fokusgrupper[2]	15.156			15.156	15.156
Indledende individuelle interviews[3]	3.674			3.674	3.674
Workshop 1-3[4]	58.787			58.787	58.787
Pilottest individuelle interviews[5]		5.511		5.511	5.511
Praksispersonale deltagelse i workshops og fokusgrupper (i alt 80,5 timer à 290 kr.)	23.345		23.345		23.345
Transportgodtgørelse praktiserende læger (3,54 kr. pr. km.)[6]	6.549			6.549	6.549
Honorering og transport ialt	107.511	5.511	23.345	89.677	113.022
Total	512.911	623.511	568.345	568.077	1.136.422

[1]Projektlederløn dækker over
2018: Den indledende behovsafdækning (rekruttering af deltagere, planlægning og udførsel) og workshop 1, 2 og 3 (rekruttering af deltagere, planlægning og udførsel)
2019: pilot test af prototype (planlægning, rekruttering og udførsel), dataindsamling fra pilot test, samt workshop 3 (planlægning, rekruttering af deltagere og udførsel)

[2]11 Praktiserende læger i 1,5 time á 918,54 kr

[3]4 praktiserende læger i 1 time à 918,54 kr.

[4]praktiserende læger (4+8+4) i ialt 64 timer á 918,54 kr

[5]6 praktiserende læger i 1 time á 918,54

[6]37 praktiserende læger til deltagelse i fokusgrupper, interviews og workshops (3+8+4+4+8+4+6) med gennemsnitlig distance på 50 km á 3,54 kr.