A mHealth-Intervention to Support the Self-Management of Multimorbid Patients in General Practices in Germany (Telepracman) – Study Protocol of a Randomized Pilot Study

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Study Protocol

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Abstract

Background: Previously we developed a structured case management for multimorbid chronically ill patients in primary care (called 'PraCMan'), delivered by Health Care Assistants in General Practice (VERAHs). The 'TelePraCMan' project aims to develop a supplementary web-based application to 'PraCMan', including a digital symptom diary in which patients can enter individual data via smartphone/tablet. This application is targeted at patients suffering from diabetes mellitus type 2, COPD, hypertension and/or chronic heart failure.

Objective: The objective of this study is to evaluate this mHealth-intervention for patients with chronic diseases, focused on patients' quality of life and self-management capabilities.

Methods: A two-arm patient-randomized pilot trial is planned, involving 200 multimorbid patients in 20 GP-practices that use 'PraCMan' regularly. Participants are randomly assigned (1:1) to receive either standard 'PraCMan' treatment or standard 'PraCMan' treatment complemented with the mHealth-intervention (TelePraCMan). As primary outcome, the health-related quality of life is measured by the German version of the Short Form Health Questionnaire (SF-12). Secondary outcomes include self-management capabilities, technical affinity, and user experience of patient and practice staff. Outcomes are measured at baseline (T0) and at follow-up after 6 months (T1). For assessment of the implementation process, GPs, VERAHs and patients will be invited to participate in interviews afterwards.

The outcomes will be compared between study arms, using multilevel regression analysis. Qualitative interviews will be transcribed and analyzed using qualitative content analysis.

Discussion: 'TelePraCMan' is one of the first mHealth-Interventions addressing multimorbid patients in primary care in the research literature.

Trial registration: DRKS, DRKS00017320, Registered 18 June 2019, <http://www.drks.de/DRKS00017320>

Background

The demographic change is associated with an increasing number of chronically ill patients leading to a rising need for care, especially in ambulatory care [1, 2]. The presence of several chronic diseases of equal importance in a person [3] is more likely in individuals of higher and advanced age [4, 5]. This poses challenges for primary care, which manages most of these patients and suffers from shortages of general practitioners (GP) [6]. To address this, innovative care models are required. One of these innovative models is the 'PraCMan'-program, which became part of the everyday care within the German federal state of Baden-Wuerttemberg in 2014 to support patients suffering from multiple chronic diseases [7].

'PraCMan' is a model for structured management of chronic diseases in primary care. Patients in 'PraCMan' not only receive regular software-supported monitoring by a care assistant in the general

practice (Versorgungsassistentin in der Hausarztpraxis/ VERAH), but are also encouraged to actively participate in the management of their disease(s) by, for example, keeping paper-based symptom diaries for chronic obstructive pulmonary disease (COPD), type 2 diabetes mellitus, hypertension and chronic heart failure. However, the uptake of self-management support in general practices is suboptimal. For instance, the diaries are not handed out to all patients and, if handed out, they often appear to be filled out inaccurately. As a result, the offered symptom diaries are hardly used by patients and GPs. This is consistent with other research in chronically ill patients, which showed that 35–43% of patients do not use paper-based symptom diaries handed out by their GPs [8, 9]. Nevertheless, symptom diaries are described as an important source of information for the attending physician and can enable the patient to cope with his illnesses in a reflective manner as an important prerequisite for self-management [10]. Observation of vital signs and symptoms by multimorbid patients is an important aspect to maintain health-related quality of life [11] as multimorbidity is characterized by a strong interaction between physical impairments and the health-related quality of life [11, 12].

In the research literature, we identified only one study on a mHealth-intervention that explicitly addressed multimorbid patients in the primary care setting [13–18]. This study showed that multimorbid patients accept and use mHealth-interventions. Furthermore, the intervention was able to support them in self-management [17, 19]. Nevertheless, there arose challenges of successfully integrating the intervention into the patients' everyday life as well as into the workflows of the GP-practices [17, 18]. Significant changes in patient outcomes referring to quality of life and activation could not be shown in a four-months trial [17]. This was traced back to the small sample of the study.

Furthermore, few studies explored the acceptance and use of mHealth-interventions by older peoples in Germany generally [19–22]. Studies of acceptance and effectiveness of mHealth-interventions for multimorbid patients and older people show that further research is needed to better adapt mHealth-interventions and enhance their application in routine healthcare practice.

The project 'TelePraCMan' aims to support patients' self-management capabilities and quality of life by introducing a mHealth-intervention for monitoring in the context of 'PraCMan', an established model of structured primary care for patients with multimorbidity.

Objectives

Primary objective

The primary objective of this study is to determine whether the use of 'TelePraCMan' as an addition to the GP-practice-based care management intervention (PraCMan) has an influence on patients' health-related quality of life as compared to regular treatment via 'PraCMan' [23, 24].

Secondary objectives

We will explore the self-management capabilities and need of technical support of patients as well as GPs and VERAHs acceptance of the application. Furthermore, general technical affinity of patients, GPs and VERAHs as well as user experiences referring to 'TelePraCMan' by patients will be explored. Also, we will investigate whether the required technologies (Smartphone/Tablet) are available within the target group of multimorbid 'PraCMan'-patients. Conclusively, the general feasibility and implementation of 'TelePraCMan' into the care system will be explored.

The hypothetical working mechanisms of 'TelePraCMan' are shown in Fig. 1

[Please, insert Fig. 1 here]

Methods

This study protocol was structured based on the SPIRIT 2013 guidelines [25].

Study design

The evaluation is designed as a parallel-group, patient-randomized, multi-center pilot trial in GP-practices in the federal state of Baden-Wuerttemberg, Germany (Fig. 2). Patients will be randomized to the intervention and control group to be equally sized (1:1). Blinding of either patients or GP-practice teams was not possible due to the character of intervention.

[Please, insert Fig. 2 here]

All participating patients as well as GPs and VERAHs in the participating practices take part in the baseline measurement (T0). Patients assigned to the intervention group receive access to 'TelePraCMan' within the randomization process and will be using 'TelePraCMan' for six months. After at least six months, all participants (patients, GPs and VERAHs) will receive a follow-up questionnaire (T1). Furthermore, the patients as well as VERAHs and GPs receive an invitation to report their experiences with 'TelePraCMan' in additional interviews within the process evaluation.

Study setting

The study is being conducted in GP-practices in the federal state of Baden-Wuerttemberg in the south-west of the Federal Republic of Germany. The Department of General Practice and Health Services Research at University Hospital Heidelberg carries out the study and takes the role of the study central office.

Eligibility criteria

'TelePraCMan' addresses multimorbid patients who are enrolled in the case management program 'PraCMan'. These patients are suffering from type 2 diabetes mellitus and/or COPD and/or high blood pressure and/or heart failure.

Practices eligible for study participation have to be part of the 'PraCMan' program for a minimum of six months, covering at least 20 'PraCMan' patients.

For their participation, patients need access to an internet-ready portable device. Furthermore, patients need to be aged 18 years or older and be able to read and speak German and to give consent for study participation. Because both, patients of the control group and of the intervention group, are included in 'PraCMan', the basic quality of care remains the same. For the inclusion in 'PraCMan', patients must be insured at the sickness fund 'AOK-Baden-Wuerttemberg' and have to be enrolled in the general practice-centered care contract [26].

Intervention

'TelePraCMan' development

'TelePraCMan' was developed and programmed by the Department of General Practice and Health Services Research at the University Hospital Heidelberg. The initial objective of developing 'TelePraCMan' was to provide the various paper-based symptom diaries of the primary care case-management program 'PraCMan' digitally in an app for smartphone or tablet. In 'PraCMan', the patient should keep these symptom diaries between regular monitoring appointments with the VERAH who acts as primary user of 'PraCMan' in GP-practices [1]. To integrate GPs, VERAHS, and patients in the development process, focus groups, semi-structured interviews as well as a questionnaire including GPs, care assistants and patients were conducted in order to gain knowledge of user requirements before and alongside the app development process. After the evaluation of the results, the app was adapted and now contains an appointment manager, a manager for target agreements, and the possibility for general practices to access the symptom data via remote access to 'TelePraCMan' besides the initial basic symptom diaries. Furthermore, 'TelePraCMan' has been transformed into a web-based application. This means that the application is not installed locally on the user's smartphone or tablet. Instead, data processing takes place on independent web servers (of University Hospital Heidelberg) and access is realized via a web browser on the user's smartphone or tablet which means that an internet connection is required in order to use the app.

'TelePraCMan' features

'TelePraCMan' has four main features: 1) *Symptom diaries* for diabetes mellitus type 2, blood pressure, heart failure, and COPD, 2) an *appointment manager*, and 3) a *manager for target agreements*, which are made individually for each patient within the regular 'PraCMan' monitoring in collaboration with GP and VERAH. The symptom diaries were supplemented by 4) a *graphic progress display* of vital signs and symptoms that have been entered. Main functions of 'TelePraCMan' are listed in Fig. 3.

[Please, insert Fig. 3 here]

The patient is expected to actively enter his or her data in 'TelePraCMan'. An automatic data transmission, e.g. from the blood glucose meter is not provided. By dealing with the data, the patient should gain better awareness of the vital signs and symptoms and the influence his behaviour can have on them [27]. A reminder can be viewed on ballot screen of 'TelePraCMan' by user.

Implementation strategies

To achieve adequate participant enrolment, we financially incentivized participation of GP-practice teams and patients. Practice teams will receive a short training imparting knowledge on the use of 'TelePraCMan' and the remote access for GP-practices. Every intervention group participant also receives a step-by-step instruction manual and a configuration checklist from his GP-practice. The configuration of symptom diaries (selection of diaries, limit and target values, diary rhythm) and target agreements are individually negotiated by patient, VERAH and GP. The patient then configures 'TelePraCMan' using the configuration checklist, which contains the negotiated settings.

Outcome measures

Primary outcome

Effects on the patients' health related quality of life during the 6-months intervention period will be assessed using the German version of the Short Form 12 Health Questionnaire (SF-12 [28]).

Secondary outcome

Secondary outcomes for participation patients are defined as follows:

- The patients' self-management capabilities is measured using the German version of the "Patient Activation Measure" (PAM13-D [29]). Self-management is the hypothesized moderating variable between usage of 'TelePraCMan' and health-related quality of life according to the rationale that self-management respectively empowerment results into a better health-related quality of life. Studies showed an association between higher patient activation and a better health related quality of life [29–31].
- A questionnaire to general technical affinity (TA-EG [32]) of participating patients and a smartphone usage questionnaire (self-administered) aim to measure the general openness towards and acceptance of new or digital technology like mHealth-interventions. The self-administered smartphone usage questionnaire is a 13-items instrument that collects ownership (yes/ no), purchase (self-bought/ receive as present/ other), and frequency of use in everyday life.as well as one item set about frequency of use of various smartphone functions (5-point Likert scale with response options from 'never' to 'very often').
- The objective number and frequency of use of 'TelePraCMan' by patients is determined by log-in data of users.
- Patients' user experience of 'TelePraCMan' is measured by the User Experience Questionnaire (UEQ [33]).
- Identification of general support needs and/or potential persons giving support in dealing with 'TelePraCMan' or technical problems. This self-administered questionnaire is a 9-items instrument that measures what kind of support (e.g. family members, manual, or without support) is used in

case of technical problems and how often it used. All items rated with a 7-point Likert scale with response options from 'never' to 'always'.

- Sociodemographic data.

Secondary outcomes concerning GP-practice side (GPs and VERAHs) are:

- The general technical affinity of participating GPs and VERAHs measured with the TA-EG questionnaire [32].
- Perception and acceptance of 'TelePraCMan' by GPs and VERAHs and the compatibility with GP-practices workflows are measured with a self-administered 21-items questionnaire at baseline (T0) and a 30-items questionnaire at follow-up (T1). All items rated with a 5-point Likert scale with response options from 'disagree' to 'strongly agree'. Furthermore, there is a field for 'no statement' for each item. The follow-up questionnaire (T1) offers several fields for open answers.
- Sociodemographic data.

After finalizing the 6-months intervention period, a qualitative process evaluation consisting of semi-structured interviews with GPs, VERAHs and patients is planned to investigate the experiences were made with 'TelePraCMan' during practical use. Table 1 shows the enrolment, and the points of outcomes assessment.

Table 1
Schedule of enrolment and assessments

STUDY PERIOD				
	Enrolment	Allocation	Post-allocation	Close-out
TIMEPOINT	-T0	0 month (T0)	6 months (T1)	7 Months
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTION:				
Provision of ,TelePraCMan'				
ASSESSMENTS (PATIENTS):				
SF-12		X	X	
PAM13-D		X	X	
TA-EG		X		
Smartphone usage		X		
Log-In data			X	
UEQ			X	
Support with technical problems		X	X	
Socialdemographic data		X		
Semi-structured Interview				X
ASSESSMENTS (GPs AND VERAHS):				
TA-EG		X		
Perception and acceptance		X	X	
Sociodemographic data		X	X	
Semi-structured Interview				X

Sample size

In order to be able to calculate a meaningful sample size for the study, recommendations refer to include at least 50 participants per arm to achieve a power of 80% and an effect size of $d < 0.1$ (2-side significance level of 5%) [34]. For the randomized trial we assumed a small effect size because studies

measuring health-related quality of life with SF-12 with comparable populations showed no significant effects after four month [17] or showed significant effects at the earliest after 24 month [26]. Since the randomized study in this case has a duration of only six months, a lower effect would suffice as an indication of the effectiveness of 'TelePraCMan'. Because the heterogenous combination of chronically diseases by multimorbid probands and a drop-out rate up to 26% in studies with comparable interventions [15, 35],[18] we operate with a total of 100 participants per arm in order to be able to consider a spectrum of chronically disease combinations as broad as possible in a later subgroup analyses. A comparable intervention study in a similar population and setting shows an intraclass correlation (ICC) of 0,01 at practice level [36]. This minimal effect has no noticeable influence on the power, so that we do not explicitly calculate the design effect D [37]. In conclusion, a total of 100 patients per arm is targeted.

Recruitment

To reach the sample size, hundred selected GP-practices participating in 'PraCMan' will be informed by letter and/or fax about the study and will be asked for their support in patient recruitment and study conduction. Practices size and geographical closeness are primary selection criteria. The aim is to recruit a maximum of 20 GP-practices with a sufficient number of 'PraCMan' patients from all over the federal state of Baden-Wuerttemberg.

The recruitment of the participating patients is carried out by the GP-practices. Patients who meet the inclusion criteria will be addressed by the participating GP-practices and will be informed verbally about the aim and content of the study by the VERAH. If the patient is interested to participate in the study, he receives two sets of information material – one for the intervention group and one for the control group. After reading the information material, the patient can formally agree to participate in the study, knowing that due to the randomization process he might end up in either in the intervention or in the control group.

Before study enrolment, practice teams will receive a short training imparting knowledge on the use of 'TelePraCMan' as well as on the recruitment and randomization processes.

Interviews

Interviews with GPs, VERAHs and patients will be conducted after completing the 6-months intervention period, to evaluate the implementation strategy. For this, patients participating as part of the intervention group receive a letter from their GP-practice containing the T1-questionnaire as well as an invitation to participate in an interview dealing with their 'TelePraCMan'-experiences. Patients interested in interview participation are asked to directly contact the study central office.

Furthermore, participating GPs and VERAHs will be recruited for semi-structured interviews after the first patient the practice recruited finishes the 6-months intervention period.

Patients' and practice team members' interview participation will be financially rewarded.

Randomization

Randomization of the patients is executed by practice staff on patient level. After the patients give consent to study participation, they will be handed out sealed envelopes with the corresponding group membership. The sealed envelopes will be prepared by the study central office beforehand ensuring that their content cannot be inspected by the GP-practices until they are opened by the patients. For the randomization, patients are randomly assigned to either the intervention or the control group by lot. This procedure is constructed to result in equally sized groups. Blocks of ten Patient-IDs will be individually matched with five control-group and five intervention-group notes.

Because the intervention cannot be blinded, all study members are able to know the group assignment of a patient from the moment of opening the envelope on. This is necessary to perform all further processes in this study as guarding the patient within the installation process as well as comparing data of the two study groups.

Data collection and management

Questionnaire

Paper-based questionnaires for participating patients at baseline (T0) and follow-up (T1) are stored in the Investigator Site File (ISF) in the GP-practices. With recruitment and allocation, the patients receive the baseline questionnaire (T0) and a post-paid envelope. The completed questionnaires will be sent by mail to the study central office by patients. After six months, the GP-practice will be given the follow-up questionnaire (T1) and a post-paid envelope to the patient, who sends the filled in questionnaire by mail to the study central office, too.

The paper-based questionnaires for participating GPs and VERAHS at baseline (T0) and a post-paid envelope are handed out to GP-practice teams at the enrolment in study face-to-face or by mail by researchers of the study central office. With the mail for recruitment to the interviews for the process evaluation, the GP-practice teams receive the follow-up questionnaire (T1) and a post-paid envelope, to send the completed questionnaire via mail to the study central office. Paper-based documents will be stored in the study central office at the Department of General Practice and Health Services Research at University Hospital Heidelberg.

Interviews

Semi-structured interviews will be conducted as face-to-face or telephone interviews by researchers of the study central office. The estimated duration for the interviews will be a maximum duration of one hour. All interviews will be audio-recorded, transcribed verbatim and stored on servers of the University Hospital Heidelberg. The transcripts of interviews will contain pseudonymized data only.

Data analysis

Data will be analyzed in accordance with the CONSORT-EHealth V1.6.2. statement [38]. Intention-to-treat analysis will be performed in the primary analysis. Descriptive statistics will be used to summarize characteristics of staff of GP-practices and participants by group. The primary and secondary outcomes at follow-up will be compared between study arms, adjusted for baseline values and potential confounders in a multiple regression analysis. To explore the impact of contextual factors (differences between participating practices), we will apply a multilevel regression that considers the hierarchical structure of data [37]. Additional sensitive analyses will be conducted as per-protocol analysis in the intervention group (i.e. regular users of the intervention).

Missing data of multi-item scales will be handled according to questionnaire guidelines. In case of missing data in SF-12 no score can be calculated due the weighting of the questions [39]. If no guideline is available for the other questionnaires, then items will be imputed with the Expectation-Maximization-Algorithm.

The qualitative data collected via semi-structured interviews at close-out will be fully transcribed and a deductive thematic content analysis [40] will be conducted, guided by the checklist for 'Tailored Implementation for Chronic Diseases' (TICD) [41] using the framework method [42].

Discussion

Usage of 'TelePraCMan' is expected to contribute to improve the self-management of multimorbid patients and, thus, to reinforce the feeling of control over one's own well-being. The acceptance and interest by patients as well as GP-practices regarding mHealth-interventions in the GP-care setting is expected to be a critical factor. Especially among older, multimorbid persons, technologies such as smartphones or tablets are not fully established, although there is a positive trend [43]. If the results show positive effects, then 'TelePraCMan' will be adjusted for further use and research.

The only comparable study showed no effects on health-related quality of life [17], and problems with integration in GP-practices workflow [18]. Nevertheless, in supplementary interviews the patients still reported increased self-confidence and motivation as a result of the intervention [17].

Therefore, a small effect on the health-related quality of life can be expected for our study. However, the fact that 'TelePraCMan' builds up on the already established GP-practice based care-management 'PraCMan' could lead to better integration into the practice's workflow and a measurable higher quality of life for participating patients.

Strengths and Limitations

Since 'TelePraCMan' is a supplement to 'PraCMan' and not a stand-alone intervention, the results may not be easily transferred to other settings. Given the characteristics of the intervention, the participating patients and the treating GP-practices know which patients are in the intervention group or control group. Therefore, performance bias cannot be excluded.

'TelePraCMan' is one of the first mHealth-interventions explicitly designed for multimorbid patients. If it gets accepted by GP-practices' staff and patients and proves as effective, 'TelePraCMan' in combination with 'PraCMan' will contribute to benefit patients' individual treatment plan. Furthermore, potential health complications could possibly be identified earlier. An advantage of the study is the relatively equal care of patients in the 'PraCMan' care context. This limits the influence of heterogeneous medical care on the results. From a scientific perspective, the results of the study can contribute to a better understanding of the acceptance and effectiveness of mHealth-interventions among multimorbid patients and elderly people.

Abbreviations

COPD
chronic obstructive pulmonary disease; GP:General practitioners; GP-practice:General practitioner practice; ISF:Investigator Site File; PRAM 13-D:German version of the "Patient Activation Measure" questionnaire; TA-EG:questionnaire to general technical affinity; TICD:Tailored Implementation for Chronic Diseases; UEQ:User Experience Questionnaire; VERAH:Care assistant in GP-practice;

Declarations

Ethics approval and consent to participate

The study protocol has been submitted to and approved by the ethics committee of the Medical Faculty Heidelberg (S-092/2019) as well as the ethics committee of the State Medical Council of Baden-Wuerttemberg (B-F-2019-073) prior to the start of the study.

All study participants give their written consent for participation. In case of the conducted field study, participants gave their consent by submitting the questionnaire.

Consent for publication

Not applicable

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analyzed during the preparation of this study protocol.

Competing interests

Dr. Freund and Dr. Szecsenyi reports about a patent with royalties paid for the PraCMan Cockpit software. The authors not named here declare that they have no competing interests.

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Authors' contributions

Study concept and design involved LW, AW, TF and JS. NL, LW and AW drafted the original manuscript. Critical revision of the manuscript for important intellectual content involved JS, TF, AM and MW.

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Figures

Figure 1

Hypothetical working mechanism of 'TelePraCMan'

Figure 2

Design and timeframe of the TelePraCMan trail

Figure 3

Main features of 'TelePraCMan'. The wallpaper of the smartphones was created by Bartekhdd and was downloaded from <https://pixabay.com/de/vectors/smartphone-symbol-moderne-schwarz-1557796/>, Accessed 12. May 2020.

Supplementary Files

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