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Piloting of the virtual telecare technology 'Addison Care' to promote self-management in persons with chronic diseases in a community setting: protocol for a mixed methods user experience, user engagement and usability pilot study

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ABSTRACT (278 words)

Introduction: Chronic diseases in older adults are one of the major epidemiological trends of current times and leading cause of disability, poor quality of life, high health care costs, and death. Self-management of chronic diseases is essential to improve health behaviors and health outcomes. Technology-assisted interventions have shown to improve self-management of chronic diseases. Virtual avatars designed for use by older persons can be a key factor for the acceptance of these technologies. Addison Care is a home-based telecare solution equipped with a virtual avatar named Addison, connecting older persons with their caregivers via an easy-to-use technology. A central advantage is that Addison care provides access to self-management support for an up-to-now highly underrepresented population - older persons with chronic disease(s) - which enables them to profit from e-health in everyday life.

Methods and analysis: A pragmatic, non-randomized, one-arm pilot study applying an embedded mixed-methods approach will be conducted to examine user experience, usability, and user engagement of the virtual avatar Addison. The pilot study will take place during the second and third quarter of 2022. Participants will be at least 65 years old and recruited from hospitals during the discharge process to home care. Standardized instruments and survey-based assessments, semi-structured interviews and think-aloud protocols will be used. The study seeks to enroll 20 patients that meet the criteria.

Ethics and dissemination: The study protocol has been approved by the ethics committee of the German Society for Nursing Science (21-037). The results of the study are intended to be published as articles in high quality peer-reviewed journals and disseminated through conference papers.

Trial registration number: The pilot study is registered in the German Clinical Trials Register (ID: DRKS00025992).

Keywords: Telecare, virtual avatar, older people, chronic disease, self-management, pilot study, user experience, e-health;

ARTICLE SUMMARY

- This pilot study provides an opportunity to explore the acceptability of and experiences with a potentially beneficial e-health technology in the underrepresented population of chronically ill older persons.
- The mixed-methods study design will provide a deep and broad insight on usability, user experience and user engagement of Addison care as a German-speaking, culturally adapted virtual avatar.
- This investigation evaluates the efficacy of a sophisticated virtual avatar, Addison, in assisting with many crucial health management tasks – including medication management and health vitals monitoring.
- A focus on barriers to user-engagement for those who are technologically hesitant will provide rich information concerning how best to design virtual avatars and e-health technologies to match user needs and mental models.
- The primary limitation of this study is the relatively small sample size due to our selective inclusion criteria, which may diminish the ethnic and socio-economic diversity of our sample.

BACKGROUND

Societies across the globe are facing a significant shift in age demographics whereby older adults are becoming an increasingly larger group within their population. This phenomenon is one of the most salient economic, social, and medical issues of current times.[1] Aging is the greatest risk factor associated with a majority of chronic diseases, as well as increasing the risk of multimorbidity. Between 34% and 61% of older adults have multimorbidity.[2] Multimorbidity can have consequences such as disability and functional decline, poor quality of life, social isolation, depression, and high health care costs.[3, 4]

Patients themselves have an integral role in the management of their chronic disease.[5] Factors that influence effective self-management of chronic disease include: experience, skill, motivation, culture, confidence, habits, physical and mental function, social support, and access to care.[6]

Self-management of chronic diseases is defined as the response to signs and symptoms when they occur, with the goal of patients playing an active role in optimising health outcomes and minimizing the impact of their conditions.[6] Self-management support refers to patient, healthcare professional, and healthcare system interventions aimed to improve self-management behaviours.[7] Self-monitoring vitals [8] and medication adherence have been recognized as two of the most essential self-management activities performed by patients to promote their health.[9]

Although interventions designed to promote self-management in chronic diseases have traditionally been offered in-person, delivering these interventions remotely utilizing available technology (e.g. mobile smart phones, Internet, interactive voice response, telephone, virtual reality) has become more prevalent.[10] These technology-assisted interventions have shown to improve self-management and health status.[11, 12]

Digital information technologies support people with care requirements to maintain their independence, improve quality of life, increase health literacy and aid caregivers in their duties.[13, 14] Telehealth is one of the fastest-growing sectors in health care. The term refers to a broad array of provider-to-patient communication and has been defined as using telecommunications, information technologies, and devices to share information and to provide clinical, population health, and administrative services at a distance.[15] Remote patient monitoring is a widely used telehealth intervention that can effectively support self-management in patients with chronic diseases.[7]

Remote Patient Monitoring

Remote Patient Monitoring (RPM) is a promising solution for facilitating the patient-physician relationship while addressing the shortage of healthcare workers today. Through robust advances in technology, RPM has matured from simple telephone interviews to real-time tracking of biometrics.

RPM technology now has the capability to further simulate human interaction as well as personalize the telehealth experience to make adoption more likely for those who are technologically hesitant.

Research concerning the efficacy of RPM has spanned the topics of post-operative rehospitalization, chronic disease management, medication adherence, and quality of life and has shown promising results [16-18]. Research has also shown that patients may find RPM and telehealth more convenient for them compared to more traditional forms of care.[19]

However, RPM technology can only benefit patients if they choose to actively interact with the devices. In a study concerning the effect of RPM engagement on type II diabetes, Michaud et al. [20] found that those who took vital measurements more often saw a greater reduction in HbA1c levels and BMI and also found that those who interacted with their system more frequently saw benefits to their knowledge on how to manage their disease. Impediments to RPM adoption may simply stem from the 'novelty' of the technology and a lack of prior RPM interaction. As compared to younger users, elderly users also face unique challenges that are a direct result of aging – such as declines in dexterity, hearing, and vision. As a result, researchers have identified that improving ease of navigation for task completion, ensuring appropriate size and color of font, and properly configuring the size of the hardware itself are paramount in addressing technological hesitancy.[21]

Virtual Avatars

RPM systems have begun to incorporate graphical user interfaces that can improve ease of use as well as personify the experience for the user through virtual avatars. Virtual avatars are an emerging feature in RPM that has shown propitious results in terms of user engagement, health education, and self-care behavior.[22]

One important factor in the receptiveness of patients to virtual avatars is the avatar's appearance. Bott [23] investigated the impact of a virtual pet avatar to deliver surveys to older clients. They found that those who interacted with the avatar experienced lower rates of delirium, fewer falls, and decreased loneliness. However, research has generally shown that anthropomorphic characteristics are often

preferable for virtual healthcare avatars [24] – as well as similarities in appearance between the avatar and the user.[25] Previous literature has revealed that when designing virtual agents for older persons, key factors related to acceptance of technology include conversational latency, gamification, and artificially intelligent lexicon.[26]

User experience and technology acceptance among older persons

Understanding how older adults perceive technology and virtual avatars may lead to improvements in the accessibility, acceptability, and adoption of virtual avatars among older persons with chronic diseases. This can be accomplished through user experience (UX) research, wherein the overall experience of the user is assessed through measures related to usability, user engagement, usefulness, function, credibility, and satisfaction with the technology.[27] While behavior, cognition, and affect are important defining components of user engagement [28], learnability, efficiency, memorability, few errors and satisfaction are defining components of usability.[29] UX is based upon User-Centered Design (UCD), wherein the needs and characteristics of the end user become the focus of technology design and development, with the intention of higher acceptance and fewer user errors.[30]

Theories that predict and explain health technology acceptance and use can help to tailor the technology to specific patient needs. One of the more recent models, the Unified Theory of Acceptance and Use of Technology (UTAUT) [31], posits that a person's intent to use (acceptance of technology) and usage behavior (actual use) of a technology is predicated by the patient's performance and effort expectancy of the technology. The UTAUT also suggests social influence and facilitating conditions as determinants of behavioral intention to use the technology.[31, 32] Most older persons are significantly less adept at technology use than the general population, with technology anxiety being a major influence on older users' intent to use technologies.[33] However, older adults are interested in integrating new technologies into their healthcare.[34] Studies confirm the applicability of the UTAUT in the context of Telecare services among older persons.[35]

Intervention: Addison Care Tablet Personal Computer (PC)

The present research pilots an intervention provided by Addison Care [36], which is an innovative home-bound connected virtual RPM platform for individuals living with chronic disease. A 3D-animated nurse named 'Addison' is the center of interaction between the system and its users, personifying the telehealth experience for the user. The pilot study encompasses two health-related functions of Addison Care: 'Addison' supporting the user in self-monitoring relevant vitals (blood pressure, weight, pulse and oxygen saturation) as well as medication schedule adherence. This is achieved by offering reminder and monitoring functionalities (see Fig. 1).

[Figure 1 about here]

The Addison Care hardware consists of a tablet PC with a speaker, a microphone module, and a touch screen (see Figure 1). The tablet connects with Bluetooth vitals measuring devices and can be installed in the user's home. Avatar technology combined with natural language understanding and automatic speech recognition provides users with effective natural interaction with the assisting technology.[22, 26] Subtitles, vital signs, and medications are graphically illustrated on the Addison Care interface to enable clear communication between user and virtual agent.

The Addison Tablet PC is connected to a web-based dashboard that allows access to user data, including vitals measurements and medication reminders. For the pilot study, medication plans, reminder-options, and contact information are managed by members of the study team, who also act as a support team for the technical set-up and in case of technical problems. The intervention in this study involves voice-driven audio-centered interaction between Addison and users in German, as well as the implementation of a German touch screen interface. Introduction of Addison Care to German users requires adaption of the original technology to ensure a good cultural fit. Adaptations were made to the surroundings of the avatar, as well as to Addison's mannerisms. Additionally, changes were made to the system to ensure a good fit between system and real life in terms of interactive elements (from basics ensuring appropriate data and time formats to more complex elements like making sure the avatar interacts in a culturally appropriate manner with the user). Voice and touch interaction

modes are currently adapted from English into German. All piloted features of Addison Care are shown in Fig. 1.

Objectives

While other studies have provided insight into the potential of digital health technology and virtual avatars, the vast majority have been tested within laboratory settings, where older adults were unable to interact with the technology in a natural setting. Additionally, the digital health systems and virtual avatars were not culturally adapted after development.

Framed by the UTAUT, the overall study aims to explore the feasibility, acceptability, experience, engagement, and usability of the culturally tailored health technology and the virtual avatar Addison for self-management for older patients with chronic diseases in their own home.

METHODS AND ANALYSIS

A pragmatic, non-randomized, one-arm pilot study applying an embedded mixed-methods approach will be conducted to examine the primary outcomes 'user experience', 'usability', and 'user engagement' of the virtual avatar Addison three times within the use span. 'Embedded' refers to the integration of qualitative methods into a quantitative methodology framework, or vice versa, to provide enriched insights or understanding into the phenomena of interest.[31, 37] The study design is pluralistic, problem-centered, real-world applicable, and focused on the consequences of actions, stemming from pragmatism as a research paradigm.[37] The present protocol followed the SPIRIT guidelines (see Supplementary 1).[38] Data collection will take place during the second and third quarter of 2022.

Recruitment criteria and process

Eligible patients will be identified by medical specialists in German hospitals through the following criteria:

- planned patients transition from hospital to extramural care
- three to nine drugs (regular intake of drugs, no status of hypermedication)
- no moderate-to-severe cognitive impairment or severe psychiatric disease
- 65 years or older with a chronic health condition
- ability to speak and understand German language

Provided that these criteria are met and general interest in using health technology is expressed, information about the pilot study and the intervention will be shared. If a patient expresses the will to participate, a meeting with the support team will be arranged while the patient is still at the hospital. Potential participants will be informed of all aspects of the study through verbal instruction and written materials (Figure 2, Encounter 1). After written informed consent is provided, living situation and socio-demographic data will be assessed by research assistants.

Setting and sample size

Addison Care will be piloted in participants´ homes after their discharge from hospital for two consecutive weeks. In Encounter 2 (see Figure 2) within 1 day after the informed consent is provided, the support team will provide first instructions on Addison Care while the participant is still hospitalized. First adjustments of reminders, medication plan, and vital measurements will be provisioned for the use of Addison Tablet PC at home. This study seeks to enroll 20 patients. The sample size is an adequate number to evaluate study feasibility, test the study procedures and explore the user experience.[39, 40]

Patient and public involvement

In advance of the pilot study, older adults assisted in the development of the data collection materials and pre-testing of Addison Care. However, patients and the public were not involved in the development of the research question, outcome measures and the design of the study.

Outcomes, Instruments, and Variables

Building upon the theoretical concepts of technology acceptance (UTAUT), we will assess user experience, usability, and user engagement (primary outcomes), as well as participant background information (e.g. sociodemographic, care provision) and health status-associated phenomena (functional status, quality of life and wellbeing, loneliness, depression, and medication adherence) using standardized, quantitative and semi-standardized qualitative research instruments (see Figure 2).

Standardized research instruments

User experience. The German version of the User Experience Questionnaire (UEQ) [41] will be used to assess user experience. The UEQ consists of 26 items along six dimensions: attractiveness, transparency, efficiency, controllability, simulation, and originality.[42]

Usability. To assess the usability of Addison Care, the validated German version of the System Usability Scale (SUS) will be applied.[43] The SUS [44] consists of 10 items and is a standardized, generic instrument for assessing the usability of technical applications, mobile applications, or devices.

User engagement. Automatic system and data logging information will be used to measure user engagement in terms of intensity and type of interactions between users and Addison Care. This non-participatory data collection, i.e. documenting data using automatically protocolled technical variables without having asked questions or the presence of an observer, will provide essential information on the actual use, used functions, and user engagement with certain contents of the product of interest.[45-47]

Functional status. The German translation [48] of the Instrumental Activities of Daily Living (iADL) scale [49] will be applied to assess patients' functional status in terms of activities of daily living. The iADL is a standardized instrument that measures functionality related to eight domains of daily living.[50]

Quality of life. Health-related quality of life will be measured by the German version of the Short-Form-8-Questionnaire (SF-8).[51]

Loneliness. To assess participants' perception of social isolation and loneliness, the shortened, 3-item German version [52, 53] of the UCLA (University of California, Los Angeles) Loneliness Scale will be applied.

Depression. The German translation [54] of the Geriatric Depression Scale (GDS) will be used to evaluate the presence of depression.[55, 56] The 8-item version will be applied to make the survey as time-efficient as possible.[57]

Medication adherence. Participants' adherence to their medication regimen will be measured by the Stendal Adherence with Medication Score (SAMS).[58] SAMS consists of 18 items, assessing fully adherent to nonadherent medication behaviour.[59]

Self-management. To assess participant´s Self-Efficacy for Managing Chronic Diseases (SESG6), the German version of the 6-item scale will be used.[60]

Technology proficiency, readiness, and expectations. A standardized face-to-face interview prior to the use of Addison Care ('pre-use interview') will be performed to collect information on participant technology proficiency and readiness (7 items) in terms of experience with and use of general information and communication technologies (3 items) as well as expectations regarding the upcoming use of the Addison Care technology (6 items). These closed-ended questions were derived from empirical and theoretical literature [31, 32, 61] and further adapted by the research team.

Sociodemographic and care provision variables. Sociodemographic and care-relevant variables will be collected by means of a short, standardized 9-item questionnaire. Participants' age, gender, living situation, place of residence in terms of urbanization, care provision by relatives, and care provision by ambulant/mobile care service will be assessed using closed-ended questions. Information on documented primary diagnoses and existing additional chronic diseases will be collected using open-ended questions and categorized applying the 11th revision of the International Classification of Diseases and Related Health Problems (ICD-11).[62]

Semi-standardized research instruments

First experiences and encountered technical obstacles. A qualitative, semi-structured brief telephone interview ('mid-use interview') with users after one week of Addison interaction will be conducted. Information about users' experiences to date, as well as previous effort and encountered challenges in using the Addison Care technology will be collected. The user reports are to be recorded in an open-ended documentation sheet.

User experience, fulfilled expectations, perceived enabling conditions for use and technology's social influence, and health behaviour. A comprehensive qualitative, semi-structured, face-to-face interview will explore participants' perspectives with reference to the fulfilled expectations after the use of Addison Care ('post-use interview'), perceived enabling conditions, and social influence in the use of the technology, as well as the participant's experiences and adaptions of health behaviour. The interview guide questions on user experience are based on the respective literature on UX research [63], those on conditions and technology's social influence along the main factors of the UTAUT model [31, 32], and those on health behaviours were developed against the background of the Health Action Process Approach (HAPA) [64]. The interview will be audio-recorded and transcribed. With reference to the embedded mixed-methods approach, the four most striking individual ratings of the previously collected standardized User Experience Questionnaire (UEQ) will be thematised and perceived changes in secondary outcomes (functional status, quality of life, loneliness, depression, medication adherence) will be assessed using open-ended questions. To address their perspectives on the use of Addison Care, an optional topical block of guided questions will be operationalized.

Task performance scenario and think-aloud protocol. Finally, to gain insight into users' thoughts, decision-making processes, and how they experience the Addison Care technology, a structured observation with an accompanying think-aloud protocol will be applied.[63, 65] Participants will be asked to perform a set of specific tasks with Addison Care while verbally expressing their immediate

thoughts, and explaining their reactions during system interaction. Task performance and participant comments will be documented using a structured observation sheet.

[Figure 2 about here]

User safety and data management

During the two weeks study period, medical emergencies, acute deterioration in health or care needs, patients' feelings of insecurity, or hospital admissions will constitute reasons to end the participation early. Formal health services in the community setting will be informed about the use of Addison Care by their clients. Informal caregivers of the participants will be educated about Addison Care and are instructed to contact the support team in need of help (see Figure 2).

Figure 2 provides detailed information on the different data retrieved during participants' enrollment. Personal information of participants will be accessed by the support team only, who will monitor the dashboard and assist with any user problems. Dashboard access is granted by login data provided by Addison Care USA.

All data retrieved empirically (see figure 2) will be saved on study-specific computers during data collection and stored in password-protected folders on the support team storage after completed data collection. User engagement data will be stored on Addison Tablet PC for short periods of time but will be regularly exported onto the server from the clinical dashboard and after the end of the pilot study transferred to study-specific computers. All personal data will be stored at a server in Berlin in Germany and encrypted. According to European Union General Data Protection Regulations, participants have the right to view all stored data or choose to delete their data at any given time as long as their data has not been anonymized by code yet.

Ethical considerations

This pilot study was approved by the ethics committee of the German Society for Nursing Science (21-037) to ensure that the research is done in accordance with the Declaration of Helsinki and in line with

the current legislation authority. The pilot study is registered in the German Clinical Trials Register (ID: DRKS00025992)

Analysis

Various data will be organized and triangulated in data sets Quan 1-4 and Qual 1-3 (see Figure 2) for analysis that fit the relevant phenomenon of interest. Final integration of overall results will take place upon conclusion of the study [37] and will be summarized with a joint display by using a mixed methods matrix.[66]

Participants` characteristics will be statistically described using information on socio-demographics, living and care provision, quality of life, health literacy, activities of daily living, and medication adherence (Quan 1, Figure 2).

A thematic content analysis of the qualitative data gained from interviews and observations in encounters 3, 4, and 5 (see Figure 2) will be performed, expanding the deductively developed code by inductive inputs.[67] Deductive codes prepared from theoretical pre-considerations will include the concepts of user experience as well as usability. Coding strategy will separate the two phenomena during the coding process. User experience results will be produced by triangulating the results of the User Experience Questionnaire (Quan 3) as well as code system elements gathered in qualitative data sets (Qual 1, 2, 3). These three data sets will provide usability results after interviews are transcribed and coded. The codes will then be merged with the SUS results (Quan 3) to get a clear picture of obstacles and acceptance. User Engagement data will track usage events like logins, reminders, and overall Addison-user-interaction over the 2-week usage period - resulting in data set Quan 4 (see Figure 2). All quantitative data will be analyzed using common descriptive statistics.

RESULTS

The pilot study will take place during the second and third quarter of 2022. Outcomes will be published in peer-reviewed medical journals and presented at international conferences.

DISCUSSION

Overview

This protocol presents research that assesses the feasibility, acceptability, experience, engagement, and usability of Addison Care – a health technology and virtual avatar for older persons with chronic diseases in their own home.

For this purpose, we culturally adopted the Addison Care technology and its functions (tutorial, medication management, testing vital signs) to explore participants' acceptance and experiences of the health technology and the virtual avatar.

For older adults with chronic diseases, the overarching goal of self-management is to enhance their quality of life and maintain independence, all while supporting formal and informal caregivers.

The goal of this pilot study is to further our understanding of the potential issues and challenges that will be used as the foundations for a larger randomized control study.

Limitations

Possible limitations of the pilot study are the lack of results on usability or acceptance of the US American version of Addison Care that we can refer to. Cultural adaption and translation into German therefore might not be the only reason for a suboptimal user experiences. Interviews allow to gain insight into this issue. The effectiveness of the extensive data collection process has to be proven as well as the recruitment process. The highly selective sample of the pilot study will diminish ethnical or socio-economic diversity which will be introduced thoroughly in the study following the pilot. The study´s timeline may be influenced by COVID-19 pandemic recruitment-wise as well as by pandemic regulations in Germany which cannot be foreseen in the current situation. Finally, it is not the aim of the pilot study to show effects on the users' health status. But the multiple instruments for testing

health status-associated phenomena should provide adequacy to show such effects in a subsequent main study.

Contributors

SK, NaS, JD, PK, NN, JO, ES, SP, MB, MK, REM and BM participated in the design of the study protocol. SK, NaS, PK, JD, TK, and ES drafted the protocol manuscript. MB, BH, BM, SP, AW, DL, AvZ and JO critically revised and commented on its previous versions and the final version. All authors critically reviewed the manuscript and agreed on submission.

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Declarations

The study protocol has been approved by the ethics committee of the German Society for Nursing Science (21-037) and is registered in the German Clinical Trials Register (ID: DRKS00025992)

Conflict of interest

ES, BH, and MB are employees of Electronic Caregiver, Las Cruces, New Mexico, United States

Figure legend

Figure 1 Addison Care functions in German version

Figure 2 Study flow, phenomenon of interest, instruments, data sets, and settings

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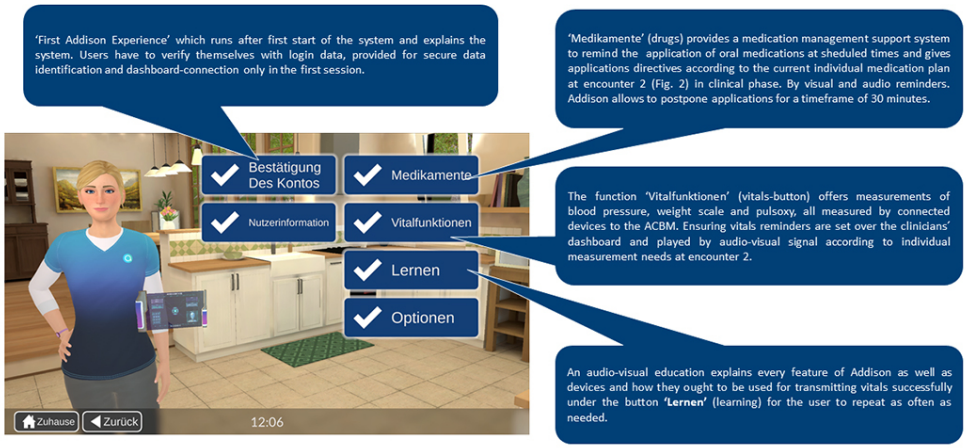
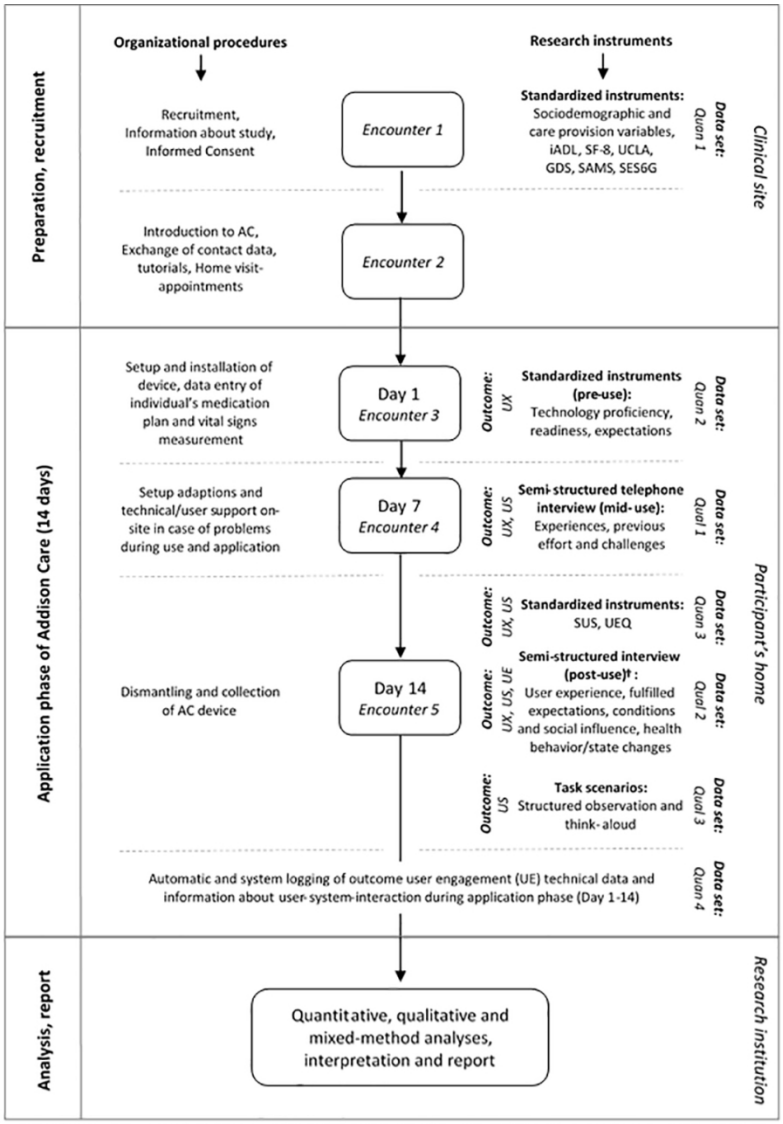


Figure 1: Addison Care functions in German version

90x50mm (300 x 300 DPI)



Notes: † in case of the presence of relatives: semi-structured interview with relatives about their impressions and experiences towards AC; AC Addison Care, GDS Geriatric Depression Scale, iADL Instrumental Activities of Daily Living Scale, SAMS Stendal Adherence with Medication Score, SES6G Self-Efficacy for Managing Chronic Disease 6-item Scale, SF-8 Health Related Quality of Life Short-Form-8-Questionnaire, SUS System Usability Scale, UCLA University of California Los Angeles Loneliness Scale, UE User Engagement, UEQ User Experience Questionnaire, US Usability, UX User Experience

Figure 2: Study flow, phenomenon of interest, instruments, data sets, and settings

90x138mm (300 x 300 DPI)

Supplement 1: SPIRIT Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Protocol adherence: addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Y:01
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Y:02
	2b	All items from the World Health Organization Trial Registration Data Set	Y
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	Y:16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Y:01, 16
	5b	Name and contact information for the trial sponsor	Y:16
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Y:16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Y:09, 13
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Y:03-06, 08
	6b	Explanation for choice of comparators	NA
Objectives	7	Specific objectives or hypotheses	Y:08
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Y:08
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Y:09, Figure 2
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Y:09
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Y:07-08, Figure 2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Y:13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Y:09-11, Figure 2
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Y:10

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Y:09, Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Y:09
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Y:09
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Y:10-13

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Y
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Y: 12-13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Y: 14-15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	X
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	X
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	X
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Y: 13
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Y: 13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	X
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Y: 14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Y: 14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Y: 09
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Y: 13-15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Y: 16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Y: 15
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	X
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	X

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

BMJ Open

Piloting of the virtual telecare technology 'Addison Care' to promote self-management in persons with chronic diseases in a community setting: protocol for a mixed methods user experience, user engagement and usability pilot study

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Primary Subject Heading:	Nursing
Secondary Subject Heading:	Health services research

Keywords:	PRIMARY CARE, PREVENTIVE MEDICINE, GERIATRIC MEDICINE

Piloting of the virtual telecare technology 'Addison Care' to promote self-management in persons with chronic diseases in a community setting: protocol for a mixed methods user experience, user engagement and usability pilot study

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ABSTRACT (297 words)

Introduction: Chronic diseases in older adults are one of the major epidemiological challenges of current times and leading cause of disability, poor quality of life, high health care costs, and death. Self-management of chronic diseases is essential to improve health behaviors and health outcomes. Technology-assisted interventions have shown to improve self-management of chronic diseases. Virtual avatars can be a key factor for the acceptance of these technologies. Addison Care is a home-based telecare solution equipped with a virtual avatar named Addison, connecting older persons with their caregivers via an easy-to-use technology. A central advantage is that Addison care provides access to self-management support for an up-to-now highly underrepresented population - older persons with chronic disease(s), which enables them to profit from e-health in everyday life.

Methods and analysis: A pragmatic, non-randomized, one-arm pilot study applying an embedded mixed-methods approach will be conducted to examine user experience, usability, and user engagement of the virtual avatar Addison. The pilot study will take place during the second and third quarter of 2022. Participants will be at least 65 years old and recruited from hospitals during the discharge process to home care. Standardized instruments, namely the User Experience Questionnaire (UEQ), System Usability Scale (SUS), Instrumental Activities of Daily Living (iADL) scale, Short-Form-8-Questionnaire (SF-8), UCLA Loneliness Scale, Geriatric Depression Scale (GDS), Stendal Adherence with Medication Score (SAMS) and Self-Efficacy for Managing Chronic Diseases Scale (SESG6), as well as survey-based assessments, semi-structured interviews and think-aloud protocols will be used. The study seeks to enroll 20 patients that meet the criteria.

Ethics and dissemination: The study protocol has been approved by the ethic committee of the German Society for Nursing Science (21-037). The results are intended to be published in peer-reviewed journals and disseminated through conference papers.

Trial registration number: German Clinical Trials Register (ID: DRKS00025992).

Keywords: Telecare, virtual avatar, older people, chronic disease self-management, pilot study, user experience, e-health;

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This pilot study provides an opportunity to explore the acceptability of and experiences with a potentially beneficial e-health technology in the underrepresented population of chronically ill older persons in a telecare setting.
- The mixed-methods study design will provide a deep and broad insight on usability, user experience and user engagement of Addison care as a German-speaking, culturally adapted virtual avatar.
- This investigation evaluates the efficacy of a sophisticated virtual avatar, Addison, in assisting with many crucial health management tasks – including medication management and health vitals monitoring.
- A focus on barriers to user-engagement for those who are technologically hesitant will provide rich information concerning how best to design virtual avatars and e-health technologies to match user needs and mental models.
- The primary limitation of this study is the relatively small sample size due to our selective inclusion criteria, which may diminish the ethnic and socio-economic diversity of our sample.

BACKGROUND

Societies across the globe are facing a significant shift in age demographics whereby older adults are becoming an increasingly larger group within their population. This phenomenon is one of the most salient economic, social, and medical issues of current times.[1] Aging increases both the risk for most chronic diseases and for multimorbidity. Between 34% and 61% of older adults are multimorbid [2],

which can have consequences such as disability and functional decline, poor quality of life, social isolation, depression, and high health care costs.[3, 4]

Patients themselves have an integral role in the management of their chronic disease.[5] Factors that influence effective self-management of chronic disease include: experience, skill, motivation, culture, confidence, habits, physical and mental function, social support, and access to care.[6]

Self-management of chronic diseases is defined as the response to signs and symptoms when they occur, with the goal that patients play an active role in optimising health outcomes and minimizing the impact of their conditions.[6] Self-management support refers to patient, healthcare professional, and healthcare system interventions aimed to improve self-management behaviours.[7] Self-monitoring vitals [8] and medication adherence have been recognized as two of the most essential self-management activities performed by patients to promote their health.[9]

Although interventions designed to promote self-management in chronic diseases have traditionally been offered in-person, delivering these interventions remotely utilizing available technology (e.g., mobile smart phones, Internet, interactive voice response, telephone, virtual reality) has become more prevalent.[10] These technology-assisted interventions have shown to improve self-management and health status.[11, 12]

Digital information technologies support people with care requirements to maintain their independence, improve quality of life, increase health literacy and aid caregivers in their duties.[13, 14] Telehealth is one of the fastest-growing sectors in health care. The term refers to a broad array of provider-to-patient communication and has been defined as using telecommunications, information technologies, and devices to share information and to provide clinical, population health, and administrative services at a distance.[15] Remote patient monitoring is a widely used telehealth intervention that can effectively support self-management in patients with chronic diseases.[7]

Remote Patient Monitoring

Remote Patient Monitoring (RPM) is a promising solution for facilitating the patient-physician relationship while addressing the shortage of healthcare workers today.

Studies concerning the efficacy of RPM has spanned the topics of post-operative rehospitalization, chronic disease management, medication adherence, and quality of life and has shown promising results.[16-20] However, RPM technology can only benefit patients who choose to actively interact with the devices. As compared to younger users, elderly users also face unique challenges that are a direct result of aging – such as declines in dexterity, hearing, and vision. As a result, researchers have identified that improving ease of navigation for task completion, ensuring appropriate size and color of font, and properly configuring the size of the hardware itself are paramount in addressing technological hesitancy.[21]

Virtual Avatars

Graphic user interfaces, which can improve the user experience and personalize the experience for the user through virtual avatars, have begun to be incorporated into RPM systems. Virtual avatars are an emerging feature in RPM that has shown propitious results in terms of user engagement, health education, and self-care behavior.[22]

One important factor in the receptiveness of patients to virtual avatars is the avatar's appearance. Bott [23] investigated the impact of a virtual pet avatar to deliver surveys to older clients. They found that those who interacted with the avatar experienced lower rates of delirium, fewer falls, and decreased loneliness. However, research has generally shown that anthropomorphic characteristics are often preferable for virtual healthcare avatars [24] – as well as similarities in appearance between the avatar and the user.[25] Previous literature has revealed that when designing virtual agents for older persons, key factors related to acceptance of technology include conversational latency, gamification, and artificially intelligent lexicon.[26]

User experience and technology acceptance among older persons

Understanding how older adults perceive technology and virtual avatars may lead to improvements in the accessibility, acceptability, and adoption of virtual avatars among older persons with chronic diseases. This can be accomplished through user experience (UX) research, wherein the overall experience of the user is assessed through measures related to usability, user engagement, usefulness, function, credibility, and satisfaction with the technology.[27] While behavior, cognition, and affect are important defining components of user engagement [28], learnability, efficiency, memorability, few errors and satisfaction are defining components of usability.[29] UX is based upon User-Centered Design (UCD), wherein the needs and characteristics of the end user become the focus of technology design and development, with the intention of higher acceptance and fewer user errors.[30]

Theories that predict and explain health technology acceptance and use can help to tailor the technology to specific patient needs. One of the more recent models, the Unified Theory of Acceptance and Use of Technology (UTAUT) [31], posits that a person's intent to use [acceptance of technology) and usage behavior (actual use) of a technology is predicated by the patient's performance and effort expectancy of the technology. The UTAUT also suggests social influence and facilitating conditions as determinants of behavioral intention to use the technology.[31, 32] Most older persons are significantly less adept at technology use than the general population, with technology anxiety being a major influence on older users' intent to use technologies.[33] However, older adults are interested in integrating new technologies into their healthcare.[34] Studies confirm the applicability of the UTAUT in the context of Telecare services among older persons.[35]

Intervention: Addison Care Tablet Personal Computer (PC)

The present research pilots an intervention provided by Addison Care [36], which is an innovative home-bound connected virtual RPM platform for individuals living with chronic disease. A 3D-animated nurse named 'Addison' is the center of interaction between the system and its users, personifying the telehealth experience for the user. The pilot study encompasses two health-related functions of Addison Care: 'Addison' supporting the user in self-monitoring relevant vitals (blood

pressure, weight, pulse and oxygen saturation) as well as medication schedule adherence. This is achieved by offering reminder and monitoring functionalities (see Fig. 1).

[Figure 1 about here]

The Addison Care hardware consists of a tablet PC with a speaker, a microphone module, and a touch screen (see Figure 1). The tablet connects with Bluetooth vitals measuring devices and can be installed in a user's home. Avatar technology combined with natural language understanding and automatic speech recognition provides users with effective natural interaction with the assisting technology.[22, 26] Subtitles, vital signs, and medications are graphically illustrated on the Addison Care interface for clear communication between the virtual agent and the user.

The Addison Tablet PC is connected to a web-based dashboard that allows access to user data, including vitals measurements and medication reminders. For the pilot study, medication plans, reminder-options, and contact information are managed by members of the study team, who also act as a support team for the technical set-up and in case of technical problems. The intervention in this study involves voice-driven audio-centered interaction between Addison and users in German, as well as the implementation of a German touch screen interface. Introduction of Addison Care to German users requires adaption of the original technology to ensure a good cultural fit. Adaptations were made to the surroundings of the avatar, as well as to Addison's mannerisms. Additionally, changes were made to the system to ensure a good fit between system and real life in terms of interactive elements [from basics ensuring appropriate data and time formats to more complex elements like making sure the avatar interacts in a culturally appropriate manner with the user). Voice and touch interaction modes are currently adapted from English into German. All piloted features of Addison Care are shown in Fig. 1.

Objectives

While other studies have provided insight into the potential of digital health technology and virtual avatars, the vast majority have been tested within laboratory settings, where older adults were unable to interact with the technology in a natural environment. Additionally, the digital health systems and virtual avatars were not culturally adapted after development.

The study aims to explore the feasibility, acceptability, experience, engagement, and usability of the culturally tailored health technology and the virtual avatar Addison for self-management for older patients with chronic diseases in their own home.

METHODS AND ANALYSIS

A pragmatic, non-randomized, one-arm pilot study applying an embedded mixed-methods approach will be conducted to examine the primary outcomes 'user experience', 'usability', and 'user engagement' of the virtual avatar Addison three times within the use span. 'Embedded' refers to the integration of qualitative methods into a quantitative methodology framework, or vice versa, to provide enriched insights or understanding into the phenomena of interest.[31, 37] The study design is pluralistic, problem-centered, real-world applicable, and focused on the consequences of actions, stemming from pragmatism as a research paradigm.[37] The present protocol followed the SPIRIT guidelines (see Supplementary 1).[38] Data collection will take place during the second and third quarter of 2022.

Recruitment criteria and process

Eligible patients will be identified by medical specialists in in German hospitals. The inclusion criteria are as follows:

- Planned patients transition from hospital to extramural care
- Three to nine drugs (regular intake of drugs, no status of hypermedication)
- 65 years or older with a chronic health condition
- Ability to speak and understand German language

The exclusion criteria are:

- Ten or more drugs per day
- Younger than 65 years old
- Moderate to severe cognitive impairment or severe psychiatric disorders

Provided that these criteria are met and general interest in using health technology is expressed, information about the pilot study and the intervention will be shared. If a patient declares the will to participate, a meeting with the support team will be arranged while the patient is still at the hospital. Potential participants will be informed of all aspects of the study through verbal instruction and written materials (Figure 2, Encounter 1). After written informed consent is provided, living situation and socio-demographic data will be assessed by research assistants.

Setting and sample size

Addison Care will be piloted in participants´ homes, located in a community setting, after their discharge from hospital for two consecutive weeks. In Encounter 2 (see Figure 2) within 1 day after the informed consent is provided, the support team will give first instructions on Addison Care while the participant is still hospitalized. First adjustments of reminder, medication plan, and vital measurements will be provisioned for the use of Addison Tablet PC at home. This study seeks to enroll 20 patients. The sample size is an adequate number to evaluate study feasibility, test the study procedures and explore the user experience.[39, 40]

Patient and public involvement

In advance of the pilot study, older adults assisted in the development of the data collection materials and pre-testing of Addison Care. However, patients and the public were not involved in the development of the research question, outcome measures and the design of the study.

Outcomes, Instruments, and Variables

Building upon the theoretical concepts of technology acceptance (UTAUT), we will assess user experience, usability, and user engagement (primary outcomes), as well as participant background information (e.g., sociodemographic, care provision) and health status-associated phenomena (functional status, quality of life and wellbeing, loneliness, depression, medication adherence, and self-management) using standardized, quantitative and semi-standardized qualitative research instruments (see Figure 2).

Standardized research instruments

User experience. The German version of the User Experience Questionnaire (UEQ) [41] will be used to assess user experience. The UEQ consists of 26 items along six scales: attractiveness (6 items, Cronbach's alpha α=0.89), perspicuity (4 items, α=0.82), efficiency (4 items, α =0.73), dependability (4 items, α=0.65), stimulation (4 items, α=0.76), and novelty (4 items, α=0.83).[41, 42] Each item represents a 7-point rating scale (-3 most negative rating, +3 most positive rating) of properties that the product under study may have. An average score is computed for each scale.

Usability. To assess the usability of Addison Care, the validated German version of the System Usability Scale (SUS) will be applied.[43] The SUS [44] consists of 10 items and is a standardized, generic instrument for assessing the usability of technical applications, mobile applications, or devices. Internal consistency has been reported to range between α =0.70 to 0.95.[45] The SUS consists of 10 items, each with five-point rating scales (1-strongly disagree to 5-strongly agree). The standardized scoring of the SUS results in a total score between 0 to 100 points using a given norm-based scoring algorithm.[45]

User engagement. Automatic system and data logging information will be used to measure user engagement in terms of intensity and type of interactions between users and Addison Care. This non-participatory data collection, e.g., documenting data using automatically protocolled technical variables without having asked questions or the presence of an observer, will provide essential

information on the actual use, used functions, and user engagement with certain contents of the product of interest.[46-48]

Functional status. The German translation [49] of the Instrumental Activities of Daily Living (iADL) scale [50] will be applied to assess patients' functional status in terms of activities of daily living. The iADL is a standardized instrument that measures functionality related to eight domains of daily living. It has reported reliability coefficients ranging from 0.85 to 0.91.[51] Each domain is measured using either three or four ability levels with 0 or 1 point per domain, resulting in a summary score of 8 points at maximum. Due to a strong reference of some items to household aspects, gender-specific scores will be used, e.g., 0 (low function, dependent) to 8 (high function, independent) for women and 0 to 5 for men, respectively.[51]

Quality of life. Health-related quality of life will be measured by the German version of the Short-Form-8-Questionnaire (SF-8).[52] The SF-8 assesses the 8 dimensions physical functioning, role physical (role limitations because of physical health), bodily pain, general health, vitality, social functioning, role emotional (role limitations because of emotional problems), and mental health, by one item each, and along two scales 'physical component summary score' and 'mental component summary score'. The items comprise of five- or six-point response scales that verbalize the extent to which each dimension is present. In addition to single-item analysis, the two summary scores will be measured using a given norm-based scoring method. Next to an adequate test-retest reliability [52], an overall internal consistency between α=0.86 and 0.92 have been reported.[53]

Loneliness. To assess participants' perception of social isolation and loneliness, the shortened, 3-item German version [54, 55] of the UCLA (University of California, Los Angeles) Loneliness Scale will be applied. Each item exhibits a five-level response scale (very often, often, sometimes, rarely, never) and will be analysed item-by-item. Cronbach's alpha for the 3-item loneliness scale was 0.72.[54]

Depression. The German translation [56] of the Geriatric Depression Scale (GDS) will be used to evaluate the presence of depression.[57, 58] The 8-item version will be applied to make the survey as

time-efficient as possible.[59] Participants are asked about selected symptoms of depressive states over the past week using a dichotomous response format (no vs. yes). The total sum score of the GDS-8 is 0-8 points. Internal consistency with α>0.80 has been shown [59]. A recommended cut-off score of GDS≥3 indicating relevant indications of depression will be applied.

Medication adherence. Participants' adherence to their medication regimen will be measured by the Stendal Adherence with Medication Score (SAMS).[60] SAMS consists of 18 items on a five-level response scale (0-4) assessing fully adherent to nonadherent medication behaviour per item.[61] Responses are summarized into a cumulative point scale (0-72), which can be categorized as fully adherent (0), moderately adherent (1-10), and not adherent (>10). An overall internal consistency of α=0.83 has been reported.[61]

Self-management. To assess participant´s Self-Efficacy for Managing Chronic Diseases (SESG6), the German version of the 6-item scale will be used.[62] The six items are rated with a 10-level Likert-type scale (1 'not at all confident' to 10 'totally confident'). A mean score over at least four of the six items will be calculated, thus allowing a maximum of two missing item responses. SESG6 has been attested a high internal consistency measure of α =0.93.[62]

Technology proficiency, readiness, and expectations. A standardized face-to-face interview prior to the use of Addison Care ('pre-use interview') will be performed to collect information on participant technology proficiency and readiness (7 items) in terms of experience with and use of general information and communication technologies (3 items) as well as expectations regarding the upcoming use of the Addison Care technology (6 items). These closed-ended questions were derived from empirical and theoretical literature [31, 32, 63] and further adapted by the research team.

Sociodemographic and care provision variables. Sociodemographic and care-relevant variables will be collected by means of a short, standardized 9-item questionnaire. Age of participants, gender, living situation, place of residence in terms of urbanization, care provision by relatives, and care provision by ambulant/mobile care service will be assessed using closed-ended questions. Information on

documented primary diagnoses and existing additional chronic diseases will be collected using open-ended questions and categorized applying the 11th revision of the International Classification of Diseases and Related Health Problems (ICD-11).[64]

Semi-standardized research instruments

First experiences and encountered technical obstacles. A qualitative, semi-structured brief telephone interview ('mid-use interview') with users after one week of Addison interaction will be conducted. Information about users' experiences to date, as well as previous effort and encountered challenges in using the Addison Care technology will be collected. The user reports are to be recorded in an open-ended documentation sheet.

User experience, fulfilled expectations, perceived enabling conditions for use and technology's social influence, and health behaviour. A comprehensive qualitative, semi-structured, face-to-face interview will explore participants' perspectives with reference to the fulfilled expectations after the use of Addison Care ('post-use interview'), perceived enabling conditions, and social influence in the use of the technology, as well as the participant's experiences and adaptions of health behaviour. The interview guide questions on user experience are based on the respective literature on UX research [65], those on conditions and technology's social influence along the main factors of the UTAUT model [31, 32], and those on health behaviours were developed against the background of the Health Action Process Approach (HAPA).[66] The interview will be audio-recorded and transcribed. With reference to the embedded mixed-methods approach, the four most striking individual ratings of the previously collected standardized User Experience Questionnaire (UEQ) will be thematised and perceived changes in secondary outcomes (functional status, quality of life, loneliness, depression, medication adherence) will be assessed using open-ended questions. To address their perspectives on the use of Addison Care, an optional topical block of guided questions will be operationalized.

Task performance scenario and think-aloud protocol. Finally, to gain insight into user thoughts, decision-making processes, and how they experience the Addison Care technology, a structured

observation with an accompanying think-aloud protocol will be applied.[67] Participants will be asked to perform a set of specific tasks with Addison Care while verbally expressing their immediate thoughts, and explaining their reactions during system interaction. Task performance and participant comments will be documented using a structured observation sheet.

[Figure 2 about here]

User safety and data management

During the two weeks study period, medical emergencies, acute deterioration in health or care needs, patients' feelings of insecurity, or hospital admissions will constitute reasons to end the participation early. Formal health services in the community setting will be informed about the use of Addison Care by their clients. Informal caregivers of the participants will be educated about Addison Care and are instructed to contact the support team in need of help (see Figure 2).

Figure 2 provides detailed information on the different data retrieved during participants´ enrolment. Personal information of participants will be accessed by the support team only, who will monitor the dashboard and assist with any user problems. Dashboard access is granted by login data provided by Addison Care USA.

All data retrieved empirically (see figure 2) will be saved on study-specific computers during data collection and stored in password-protected folders on the support team storage after completed data collection. User engagement data will be stored on Addison Tablet PC for short periods of time being but regularly exported onto the server from the clinical dashboard and after the end of the pilot study transferred to study-specific computers. All personal data will be stored at a server in Berlin in Germany and encrypted. According to European Union General Data Protection Regulations, participants have the right to view all stored data or choose to delete their data at any given time as long as their data has not been anonymized by code yet.

Ethical considerations

This pilot study was approved by the ethics committee of the German Society for Nursing Science (21-037) to ensure that the research is done in accordance with the Declaration of Helsinki and in line with the current legislation authority (see Supplementary 2). The pilot study is registered in the German Clinical Trials Register (ID: DRKS00025992).

Analysis

Various data will be organized and triangulated in data sets Quan 1-4 and Qual 1-3 (see Figure 2) for analysis that fit the relevant phenomenon of interest. Final integration of overall results will take place upon conclusion of the study [37] and will be summarized with a joint display by using a mixed methods matrix.[68]

Participants` characteristics will be statistically described using information on socio-demographics, living and care provision, quality of life, health literacy, activities of daily living, and medication adherence (Quan 1, Figure 2).

A thematic content analysis of the qualitative data gained from interviews and observations in encounters 4 and 5 (see Figure 2) will be performed, expanding the deductively developed code by inductive inputs.[69] Deductive codes prepared from theoretical pre-considerations will include the concepts of user experience as well as usability. Coding strategy will separate the two phenomena during the coding process. User experience results will be produced by triangulating the results of the User Experience Questionnaire (Quan 3) as well as code system elements gathered in qualitative data sets (Qual 1, 2, 3). These three data sets will provide usability results after interviews are transcribed and coded. The codes will then be merged with the SUS results (Quan 3) to get a clear picture of obstacles and acceptance. User Engagement data will track usage events like logins, reminders, and overall Addison-user-interaction over the 2-week usage period - resulting in data set Quan 4 (see Figure 2). To facilitate the subsequent main study, deductive codes for the area of a feasibility study are also included in the coding strategy.[70] All quantitative data will be analyzed using common descriptive statistics.

DISCUSSION

Overview

This protocol presents research that assesses the feasibility, acceptability, experience, engagement, and usability of Addison Care – a health technology and virtual avatar for older persons with chronic diseases in their own home.

For this purpose, we culturally adopted the Addison Care technology and its functions (tutorial, medication management, testing vital signs) to explore participants' acceptance and experiences of the health technology and the virtual avatar.

For older adults with chronic diseases, the overarching goal of self-management is to enhance their quality of life and maintain independence, all while supporting formal and informal caregivers.

The goal of this pilot study is to further our understanding of the potential issues and challenges that will be used as the foundations for a larger randomized control study.

One of the strengths of this study is the use of the health technology for a longer period of time and with real patients in a natural setting. Another strength lies in the cultural adaption of the health technology and its integration in a telecare framework. The integrated voice and touch interaction with the avatar 'Addison' should also contribute to improve the human-computer interaction.

Limitations

Possible limitations of the pilot study are the lack of results on usability or acceptance of the US American version of Addison Care that we can refer to. Cultural adaption and translation into German therefore might not be the only reason for a suboptimal user experience. Interviews allow to gain insight into this issue. The effectiveness of the extensive data collection process has to be proven as well as the recruitment process. The highly selective sample of the pilot study will diminish ethnical or

socio-economic diversity which will be introduced thoroughly in the study following the pilot. Within the qualitative branch of the mixed-methods study we seek sufficient richness of data but do not expect to achieve a data saturation. The study´s time line may be influenced by COVID-19 pandemic recruitment-wise as well as by pandemic regulations in Germany which cannot be foreseen at the current situation. Because we do not have an influence on the stability of the Internet connection, this could be another source of uncertainty. Finally, it is not the aim of the pilot study to show effects on the health status of the users. But the multiple instruments for testing health status-associated phenomena should provide adequacy to show such effects in a subsequent main study.

Contributors

SK, NaS, JD, PK, NN, JO, ES, SP, MB, MK, REM and BM participated in the design of the study protocol. SK, NaS, PK, JD, TK, and ES drafted the protocol manuscript. MB, BH, BM, SP, AW, DL, AvZ and JO critically revised and commented on its previous versions and the final version. All authors critically reviewed the manuscript and agreed on submission.

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Declarations

The study protocol has been approved by the ethic committee of the German Society for Nursing Science (21-037) and is registered in the German Clinical Trials Register (ID: DRKS0002599).

Conflict of interest

ES, BH, and MB are employees of Electronic Caregiver, Las Cruces, New Mexico, United States

Figure legend

Figure 1 Addison Care functions in German version (Reproduced with permission from https://electroniccaregiver.com)

Figure 2 Study flow, phenomenon of interest, instruments, data sets, and settings

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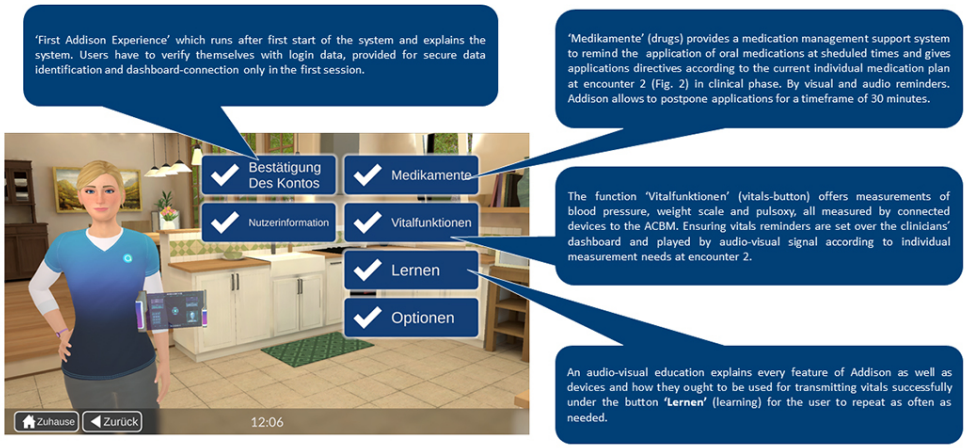
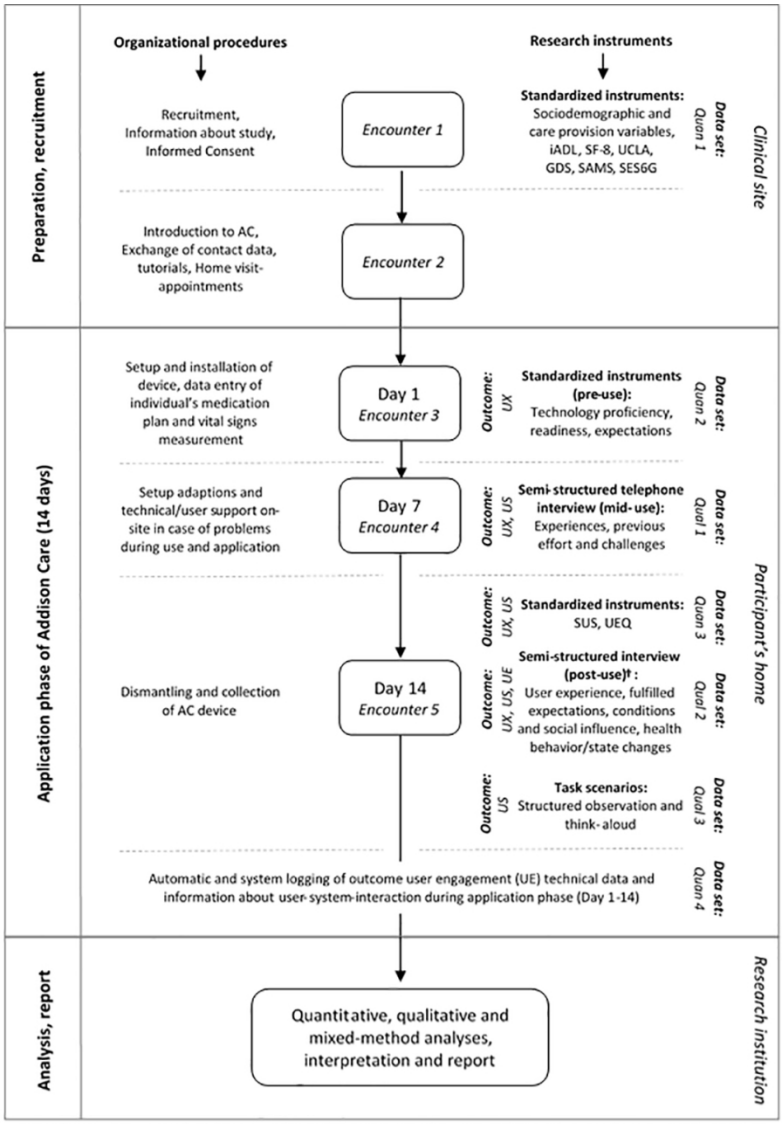


Figure 1: Addison Care functions in German version (Figure 1 reproduced with permission from https://electroniccaregiver.com)

90x50mm (300 x 300 DPI)



Notes: † in case of the presence of relatives: semi-structured interview with relatives about their impressions and experiences towards AC; AC Addison Care, GDS Geriatric Depression Scale, iADL Instrumental Activities of Daily Living Scale, SAMS Stendal Adherence with Medication Score, SES6G Self-Efficacy for Managing Chronic Disease 6-item Scale, SF-8 Health Related Quality of Life Short-Form-8-Questionnaire, SUS System Usability Scale, UCLA University of California Los Angeles Loneliness Scale, UE User Engagement, UEQ User Experience Questionnaire, US Usability, UX User Experience

Figure 2: Study flow, phenomenon of interest, instruments, data sets, and settings

90x138mm (300 x 300 DPI)

Supplement 1: SPIRIT Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Protocol adherence: addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Y:01
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Y:02
	2b	All items from the World Health Organization Trial Registration Data Set	Y
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	Y:16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Y:01, 16
	5b	Name and contact information for the trial sponsor	Y:16
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Y:16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Y:09, 13
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Y:03-06, 08
	6b	Explanation for choice of comparators	NA
Objectives	7	Specific objectives or hypotheses	Y:08
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Y:08
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Y:09, Figure 2
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Y:09
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Y:07-08, Figure 2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Y:13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Y:09-11, Figure 2
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Y:10

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Y:09, Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Y:09
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Y:09
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Y:10-13

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Y
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Y: 12-13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Y: 14-15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	X
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	X
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	X
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Y: 13
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Y: 13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	X
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Y: 14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Y: 14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Y: 09
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Y: 13-15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Y: 16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Y: 15
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	X
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	X

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

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Your proposal no. 21-037 to the ethical review committee of the German Society of Nursing Science (EK-DGP)

Dear Mr. Osterbrink,

the EK-DGP discussed and evaluated your proposal

A pilot study of Addison Care, the Virtual Telecare Technology, - PiloTT-A (application no. 21-037)

submitted 2021-11-16.

The committee decided to give you an ethical approval.

Good luck for the project!

2021-12-27

Prof. Dr. Sabine Bartholomeyczik
Chairperson EK-DGP

BMJ Open

Piloting of the virtual telecare technology 'Addison Care' to promote self-management in persons with chronic diseases in a community setting: protocol for a mixed methods user experience, user engagement and usability pilot study

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Primary Subject Heading:	Nursing
Secondary Subject Heading:	Health services research

Keywords:	PRIMARY CARE, PREVENTIVE MEDICINE, GERIATRIC MEDICINE

Piloting of the virtual telecare technology 'Addison Care' to promote self-management in persons with chronic diseases in a community setting: protocol for a mixed methods user experience, user engagement and usability pilot study

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ABSTRACT (293 words)

Introduction: Chronic diseases in older adults are one of the major epidemiological challenges of current times and leading cause of disability, poor quality of life, high health care costs, and death. Self-management of chronic diseases is essential to improve health behaviors and health outcomes. Technology-assisted interventions have shown to improve self-management of chronic diseases. Virtual avatars can be a key factor for the acceptance of these technologies. Addison Care is a home-based telecare solution equipped with a virtual avatar named Addison, connecting older persons with their caregivers via an easy-to-use technology. A central advantage is that Addison care provides access to self-management support for an up-to-now highly underrepresented population - older persons with chronic disease(s), which enables them to profit from e-health in everyday life.

Methods and analysis: A pragmatic, non-randomized, one-arm pilot study applying an embedded mixed-methods approach will be conducted to examine user experience, usability, and user engagement of the virtual avatar Addison. Participants will be at least 65 years old and will be recruited between September 2022 and November 2022 from hospitals during the discharge process to home care. Standardized instruments, namely the User Experience Questionnaire (UEQ), System Usability Scale (SUS), Instrumental Activities of Daily Living (iADL) scale, Short-Form-8-Questionnaire (SF-8), UCLA Loneliness Scale, Geriatric Depression Scale (GDS), Stendal Adherence with Medication Score (SAMS) and Self-Efficacy for Managing Chronic Diseases Scale (SESG6), as well as survey-based assessments, semi-structured interviews and think-aloud protocols will be used. The study seeks to enroll 20 patients that meet the criteria.

Ethics and dissemination: The study protocol has been approved by the ethic committee of the German Society for Nursing Science (21-037). The results are intended to be published in peer-reviewed journals and disseminated through conference papers.

Trial registration number: German Clinical Trials Register (ID: DRKS00025992).

Keywords: Telecare, virtual avatar, older people, chronic disease self-management, pilot study, user experience, e-health;

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This pilot study provides an opportunity to explore the acceptability of and experiences with a potentially beneficial e-health technology in the underrepresented population of chronically ill older persons in a telecare setting.
- The mixed-methods study design will provide a deep and broad insight on usability, user experience and user engagement of Addison care as a German-speaking, culturally adapted virtual avatar.
- This investigation evaluates the efficacy of a sophisticated virtual avatar, Addison, in assisting with many crucial health management tasks – including medication management and health vitals monitoring.
- A focus on barriers to user-engagement for those who are technologically hesitant will provide rich information concerning how best to design virtual avatars and e-health technologies to match user needs and mental models.
- The primary limitation of this study is the relatively small sample size due to our selective inclusion criteria, which may diminish the ethnic and socio-economic diversity of our sample.

BACKGROUND

Societies across the globe are facing a significant shift in age demographics whereby older adults are becoming an increasingly larger group within their population. This phenomenon is one of the most salient economic, social, and medical issues of current times.[1] Aging increases both the risk for most chronic diseases and for multimorbidity. Between 34% and 61% of older adults are multimorbid [2],

which can have consequences such as disability and functional decline, poor quality of life, social isolation, depression, and high health care costs.[3, 4]

Patients themselves have an integral role in the management of their chronic disease.[5] Factors that influence effective self-management of chronic disease include: experience, skill, motivation, culture, confidence, habits, physical and mental function, social support, and access to care.[6]

Self-management of chronic diseases is defined as the response to signs and symptoms when they occur, with the goal that patients play an active role in optimising health outcomes and minimizing the impact of their conditions.[6] Self-management support refers to patient, healthcare professional, and healthcare system interventions aimed to improve self-management behaviours.[7] Self-monitoring vitals [8] and medication adherence have been recognized as two of the most essential self-management activities performed by patients to promote their health.[9]

Although interventions designed to promote self-management in chronic diseases have traditionally been offered in-person, delivering these interventions remotely utilizing available technology (e.g., mobile smart phones, Internet, interactive voice response, telephone, virtual reality) has become more prevalent.[10] These technology-assisted interventions have shown to improve self-management and health status.[11, 12]

Digital information technologies support people with care requirements to maintain their independence, improve quality of life, increase health literacy and aid caregivers in their duties.[13, 14] Telehealth is one of the fastest-growing sectors in health care. The term refers to a broad array of provider-to-patient communication and has been defined as using telecommunications, information technologies, and devices to share information and to provide clinical, population health, and administrative services at a distance.[15] Remote patient monitoring is a widely used telehealth intervention that can effectively support self-management in patients with chronic diseases.[7]

Remote Patient Monitoring

Remote Patient Monitoring (RPM) is a promising solution for facilitating the patient-physician relationship while addressing the shortage of healthcare workers today.

Studies concerning the efficacy of RPM has spanned the topics of post-operative rehospitalization, chronic disease management, medication adherence, and quality of life and has shown promising results.[16-20] However, RPM technology can only benefit patients who choose to actively interact with the devices. As compared to younger users, elderly users also face unique challenges that are a direct result of aging – such as declines in dexterity, hearing, and vision. As a result, researchers have identified that improving ease of navigation for task completion, ensuring appropriate size and color of font, and properly configuring the size of the hardware itself are paramount in addressing technological hesitancy.[21]

Virtual Avatars

Graphic user interfaces, which can improve the user experience and personalize the experience for the user through virtual avatars, have begun to be incorporated into RPM systems. Virtual avatars are an emerging feature in RPM that has shown propitious results in terms of user engagement, health education, and self-care behavior.[22]

One important factor in the receptiveness of patients to virtual avatars is the avatar's appearance. Bott [23] investigated the impact of a virtual pet avatar to deliver surveys to older clients. They found that those who interacted with the avatar experienced lower rates of delirium, fewer falls, and decreased loneliness. However, research has generally shown that anthropomorphic characteristics are often preferable for virtual healthcare avatars [24] – as well as similarities in appearance between the avatar and the user.[25] Previous literature has revealed that when designing virtual agents for older persons, key factors related to acceptance of technology include conversational latency, gamification, and artificially intelligent lexicon.[26]

User experience and technology acceptance among older persons

Understanding how older adults perceive technology and virtual avatars may lead to improvements in the accessibility, acceptability, and adoption of virtual avatars among older persons with chronic diseases. This can be accomplished through user experience (UX) research, wherein the overall experience of the user is assessed through measures related to usability, user engagement, usefulness, function, credibility, and satisfaction with the technology.[27] While behavior, cognition, and affect are important defining components of user engagement [28], learnability, efficiency, memorability, few errors and satisfaction are defining components of usability.[29] UX is based upon User-Centered Design (UCD), wherein the needs and characteristics of the end user become the focus of technology design and development, with the intention of higher acceptance and fewer user errors.[30]

Theories that predict and explain health technology acceptance and use can help to tailor the technology to specific patient needs. One of the more recent models, the Unified Theory of Acceptance and Use of Technology (UTAUT) [31], posits that a person's intent to use [acceptance of technology) and usage behavior (actual use) of a technology is predicated by the patient's performance and effort expectancy of the technology. The UTAUT also suggests social influence and facilitating conditions as determinants of behavioral intention to use the technology.[31, 32] Most older persons are significantly less adept at technology use than the general population, with technology anxiety being a major influence on older users' intent to use technologies.[33] However, older adults are interested in integrating new technologies into their healthcare.[34] Studies confirm the applicability of the UTAUT in the context of Telecare services among older persons.[35]

Intervention: Addison Care Tablet Personal Computer (PC)

The present research pilots an intervention provided by Addison Care [36], which is an innovative home-bound connected virtual RPM platform for individuals living with chronic disease. A 3D-animated nurse named 'Addison' is the center of interaction between the system and its users, personifying the telehealth experience for the user. The pilot study encompasses two health-related functions of Addison Care: 'Addison' supporting the user in self-monitoring relevant vitals (blood

pressure, weight, pulse and oxygen saturation) as well as medication schedule adherence. This is achieved by offering reminder and monitoring functionalities (see Fig. 1).

[Figure 1 about here]

The Addison Care hardware consists of a tablet PC with a speaker, a microphone module, and a touch screen (see Figure 1). The tablet connects with Bluetooth vitals measuring devices and can be installed in a user's home. Avatar technology combined with natural language understanding and automatic speech recognition provides users with effective natural interaction with the assisting technology.[22, 26] Subtitles, vital signs, and medications are graphically illustrated on the Addison Care interface for clear communication between the virtual agent and the user.

The Addison Tablet PC is connected to a web-based dashboard that allows access to user data, including vitals measurements and medication reminders. For the pilot study, medication plans, reminder-options, and contact information are managed by members of the study team, who also act as a support team for the technical set-up and in case of technical problems. The intervention in this study involves voice-driven audio-centered interaction between Addison and users in German, as well as the implementation of a German touch screen interface. Introduction of Addison Care to German users requires adaption of the original technology to ensure a good cultural fit. Adaptations were made to the surroundings of the avatar, as well as to Addison's mannerisms. Additionally, changes were made to the system to ensure a good fit between system and real life in terms of interactive elements [from basics ensuring appropriate data and time formats to more complex elements like making sure the avatar interacts in a culturally appropriate manner with the user). Voice and touch interaction modes are currently adapted from English into German. All piloted features of Addison Care are shown in Fig. 1.

Objectives

While other studies have provided insight into the potential of digital health technology and virtual avatars, the vast majority have been tested within laboratory settings, where older adults were unable to interact with the technology in a natural environment. Additionally, the digital health systems and virtual avatars were not culturally adapted after development.

The study aims to explore the feasibility, acceptability, experience, engagement, and usability of the culturally tailored health technology and the virtual avatar Addison for self-management for older patients with chronic diseases in their own home.

METHODS AND ANALYSIS

A pragmatic, non-randomized, one-arm pilot study applying an embedded mixed-methods approach will be conducted to examine the primary outcomes 'user experience', 'usability', and 'user engagement' of the virtual avatar Addison three times within the use span. 'Embedded' refers to the integration of qualitative methods into a quantitative methodology framework, or vice versa, to provide enriched insights or understanding into the phenomena of interest.[31, 37] The study design is pluralistic, problem-centered, real-world applicable, and focused on the consequences of actions, stemming from pragmatism as a research paradigm.[37] The present protocol followed the SPIRIT guidelines (see Supplementary 1).[38] Data collection will take place between September 2022 and November 2022.

Recruitment criteria and process

Eligible patients will be identified by medical specialists in in German hospitals. The inclusion criteria are as follows:

- Planned patients transition from hospital to extramural care
- Three to nine drugs (regular intake of drugs, no status of hypermedication)
- 65 years or older with a chronic health condition
- Ability to speak and understand German language

The exclusion criteria are:

- Ten or more drugs per day
- Younger than 65 years old
- Moderate to severe cognitive impairment or severe psychiatric disorders

Provided that these criteria are met and general interest in using health technology is expressed, information about the pilot study and the intervention will be shared. If a patient declares the will to participate, a meeting with the support team will be arranged while the patient is still at the hospital. Potential participants will be informed of all aspects of the study through verbal instruction and written materials (Figure 2, Encounter 1). After written informed consent (see Supplementary 2) is provided, living situation and socio-demographic data will be assessed by research assistants.

Setting and sample size

Addison Care will be piloted in participants´ homes, located in a community setting, after their discharge from hospital for two consecutive weeks. In Encounter 2 (see Figure 2) within 1 day after the informed consent is provided, the support team will give first instructions on Addison Care while the participant is still hospitalized. First adjustments of reminder, medication plan, and vital measurements will be provisioned for the use of Addison Tablet PC at home. This study seeks to enroll 20 patients. The sample size is an adequate number to evaluate study feasibility, test the study procedures and explore the user experience.[39, 40]

Patient and public involvement

In advance of the pilot study, older adults assisted in the development of the data collection materials and pre-testing of Addison Care. However, patients and the public were not involved in the development of the research question, outcome measures and the design of the study.

Outcomes, Instruments, and Variables

Building upon the theoretical concepts of technology acceptance (UTAUT), we will assess user experience, usability, and user engagement (primary outcomes), as well as participant background information (e.g., sociodemographic, care provision) and health status-associated phenomena (functional status, quality of life and wellbeing, loneliness, depression, medication adherence, and self-management) using standardized, quantitative and semi-standardized qualitative research instruments (see Figure 2).

Standardized research instruments

User experience. The German version of the User Experience Questionnaire (UEQ) [41] will be used to assess user experience. The UEQ consists of 26 items along six scales: attractiveness (6 items, Cronbach's alpha α=0.89), perspicuity (4 items, α=0.82), efficiency (4 items, α =0.73), dependability (4 items, α=0.65), stimulation (4 items, α=0.76), and novelty (4 items, α=0.83).[41, 42] Each item represents a 7-point rating scale (-3 most negative rating, +3 most positive rating) of properties that the product under study may have. An average score is computed for each scale.

Usability. To assess the usability of Addison Care, the validated German version of the System Usability Scale (SUS) will be applied.[43] The SUS [44] consists of 10 items and is a standardized, generic instrument for assessing the usability of technical applications, mobile applications, or devices. Internal consistency has been reported to range between α =0.70 to 0.95.[45] The SUS consists of 10 items, each with five-point rating scales (1-strongly disagree to 5-strongly agree). The standardized scoring of the SUS results in a total score between 0 to 100 points using a given norm-based scoring algorithm.[45]

User engagement. Automatic system and data logging information will be used to measure user engagement in terms of intensity and type of interactions between users and Addison Care. This non-participatory data collection, e.g., documenting data using automatically protocolled technical variables without having asked questions or the presence of an observer, will provide essential

information on the actual use, used functions, and user engagement with certain contents of the product of interest.[46-48]

Functional status. The German translation [49] of the Instrumental Activities of Daily Living (iADL) scale [50] will be applied to assess patients' functional status in terms of activities of daily living. The iADL is a standardized instrument that measures functionality related to eight domains of daily living. It has reported reliability coefficients ranging from 0.85 to 0.91.[51] Each domain is measured using either three or four ability levels with 0 or 1 point per domain, resulting in a summary score of 8 points at maximum. Due to a strong reference of some items to household aspects, gender-specific scores will be used, e.g., 0 (low function, dependent) to 8 (high function, independent) for women and 0 to 5 for men, respectively.[51]

Quality of life. Health-related quality of life will be measured by the German version of the Short-Form-8-Questionnaire (SF-8).[52] The SF-8 assesses the 8 dimensions physical functioning, role physical (role limitations because of physical health), bodily pain, general health, vitality, social functioning, role emotional (role limitations because of emotional problems), and mental health, by one item each, and along two scales 'physical component summary score' and 'mental component summary score'. The items comprise of five- or six-point response scales that verbalize the extent to which each dimension is present. In addition to single-item analysis, the two summary scores will be measured using a given norm-based scoring method. Next to an adequate test-retest reliability [52], an overall internal consistency between α=0.86 and 0.92 have been reported.[53]

Loneliness. To assess participants' perception of social isolation and loneliness, the shortened, 3-item German version [54, 55] of the UCLA (University of California, Los Angeles) Loneliness Scale will be applied. Each item exhibits a five-level response scale (very often, often, sometimes, rarely, never) and will be analysed item-by-item. Cronbach's alpha for the 3-item loneliness scale was 0.72.[54]

Depression. The German translation [56] of the Geriatric Depression Scale (GDS) will be used to evaluate the presence of depression.[57, 58] The 8-item version will be applied to make the survey as

time-efficient as possible.[59] Participants are asked about selected symptoms of depressive states over the past week using a dichotomous response format (no vs. yes). The total sum score of the GDS-8 is 0-8 points. Internal consistency with α>0.80 has been shown [59]. A recommended cut-off score of GDS≥3 indicating relevant indications of depression will be applied.

Medication adherence. Participants' adherence to their medication regimen will be measured by the Stendal Adherence with Medication Score (SAMS).[60] SAMS consists of 18 items on a five-level response scale (0-4) assessing fully adherent to nonadherent medication behaviour per item.[61] Responses are summarized into a cumulative point scale (0-72), which can be categorized as fully adherent (0), moderately adherent (1-10), and not adherent (>10). An overall internal consistency of α=0.83 has been reported.[61]

Self-management. To assess participant´s Self-Efficacy for Managing Chronic Diseases (SESG6), the German version of the 6-item scale will be used.[62] The six items are rated with a 10-level Likert-type scale (1 'not at all confident' to 10 'totally confident'). A mean score over at least four of the six items will be calculated, thus allowing a maximum of two missing item responses. SESG6 has been attested a high internal consistency measure of α =0.93.[62]

Technology proficiency, readiness, and expectations. A standardized face-to-face interview prior to the use of Addison Care ('pre-use interview') will be performed to collect information on participant technology proficiency and readiness (7 items) in terms of experience with and use of general information and communication technologies (3 items) as well as expectations regarding the upcoming use of the Addison Care technology (6 items). These closed-ended questions were derived from empirical and theoretical literature [31, 32, 63] and further adapted by the research team.

Sociodemographic and care provision variables. Sociodemographic and care-relevant variables will be collected by means of a short, standardized 9-item questionnaire. Age of participants, gender, living situation, place of residence in terms of urbanization, care provision by relatives, and care provision by ambulant/mobile care service will be assessed using closed-ended questions. Information on

documented primary diagnoses and existing additional chronic diseases will be collected using open-ended questions and categorized applying the 11th revision of the International Classification of Diseases and Related Health Problems (ICD-11).[64]

Semi-standardized research instruments

First experiences and encountered technical obstacles. A qualitative, semi-structured brief telephone interview ('mid-use interview') with users after one week of Addison interaction will be conducted. Information about users' experiences to date, as well as previous effort and encountered challenges in using the Addison Care technology will be collected. The user reports are to be recorded in an open-ended documentation sheet.

User experience, fulfilled expectations, perceived enabling conditions for use and technology's social influence, and health behaviour. A comprehensive qualitative, semi-structured, face-to-face interview will explore participants' perspectives with reference to the fulfilled expectations after the use of Addison Care ('post-use interview'), perceived enabling conditions, and social influence in the use of the technology, as well as the participant's experiences and adaptions of health behaviour. The interview guide questions on user experience are based on the respective literature on UX research [65], those on conditions and technology's social influence along the main factors of the UTAUT model [31, 32], and those on health behaviours were developed against the background of the Health Action Process Approach (HAPA).[66] The interview will be audio-recorded and transcribed. With reference to the embedded mixed-methods approach, the four most striking individual ratings of the previously collected standardized User Experience Questionnaire (UEQ) will be thematised and perceived changes in secondary outcomes (functional status, quality of life, loneliness, depression, medication adherence) will be assessed using open-ended questions. To address their perspectives on the use of Addison Care, an optional topical block of guided questions will be operationalized.

Task performance scenario and think-aloud protocol. Finally, to gain insight into user thoughts, decision-making processes, and how they experience the Addison Care technology, a structured

observation with an accompanying think-aloud protocol will be applied.[67] Participants will be asked to perform a set of specific tasks with Addison Care while verbally expressing their immediate thoughts, and explaining their reactions during system interaction. Task performance and participant comments will be documented using a structured observation sheet.

[Figure 2 about here]

User safety and data management

During the two weeks study period, medical emergencies, acute deterioration in health or care needs, patients' feelings of insecurity, or hospital admissions will constitute reasons to end the participation early. Formal health services in the community setting will be informed about the use of Addison Care by their clients. Informal caregivers of the participants will be educated about Addison Care and are instructed to contact the support team in need of help (see Figure 2).

Figure 2 provides detailed information on the different data retrieved during participants´ enrolment. Personal information of participants will be accessed by the support team only, who will monitor the dashboard and assist with any user problems. Dashboard access is granted by login data provided by Addison Care USA.

All data retrieved empirically (see figure 2) will be saved on study-specific computers during data collection and stored in password-protected folders on the support team storage after completed data collection. User engagement data will be stored on Addison Tablet PC for short periods of time being but regularly exported onto the server from the clinical dashboard and after the end of the pilot study transferred to study-specific computers. All personal data will be stored at a server in Berlin in Germany and encrypted. According to European Union General Data Protection Regulations, participants have the right to view all stored data or choose to delete their data at any given time as long as their data has not been anonymized by code yet.

Analysis

Various data will be organized and triangulated in data sets Quan 1-4 and Qual 1-3 (see Figure 2) for analysis that fit the relevant phenomenon of interest. Final integration of overall results will take place upon conclusion of the study [37] and will be summarized with a joint display by using a mixed methods matrix.[68]

Participants` characteristics will be statistically described using information on socio-demographics, living and care provision, quality of life, health literacy, activities of daily living, and medication adherence (Quan 1, Figure 2).

A thematic content analysis of the qualitative data gained from interviews and observations in encounters 4 and 5 (see Figure 2) will be performed, expanding the deductively developed code by inductive inputs.[69] Deductive codes prepared from theoretical pre-considerations will include the concepts of user experience as well as usability. Coding strategy will separate the two phenomena during the coding process. User experience results will be produced by triangulating the results of the User Experience Questionnaire (Quan 3) as well as code system elements gathered in qualitative data sets (Qual 1, 2, 3). These three data sets will provide usability results after interviews are transcribed and coded. The codes will then be merged with the SUS results (Quan 3) to get a clear picture of obstacles and acceptance. User Engagement data will track usage events like logins, reminders, and overall Addison-user-interaction over the 2-week usage period - resulting in data set Quan 4 (see Figure 2). To facilitate the subsequent main study, deductive codes for the area of a feasibility study are also included in the coding strategy.[70] All quantitative data will be analyzed using common descriptive statistics.

Ethics and dissemination

Ethical considerations

This pilot study was approved by the ethics committee of the German Society for Nursing Science (21-037) to ensure that the research is done in accordance with the Declaration of Helsinki and in line with

the current legislation authority (see Supplementary 3). The pilot study is registered in the German Clinical Trials Register (ID: DRKS00025992).

Overview

This protocol presents research that assesses the feasibility, acceptability, experience, engagement, and usability of Addison Care – a health technology and virtual avatar for older persons with chronic diseases in their own home.

For this purpose, we culturally adopted the Addison Care technology and its functions (tutorial, medication management, testing vital signs) to explore participants' acceptance and experiences of the health technology and the virtual avatar.

For older adults with chronic diseases, the overarching goal of self-management is to enhance their quality of life and maintain independence, all while supporting formal and informal caregivers.

The goal of this pilot study is to further our understanding of the potential issues and challenges that will be used as the foundations for a larger randomized control study.

One of the strengths of this study is the use of the health technology for a longer period of time and with real patients in a natural setting. Another strength lies in the cultural adaption of the health technology and its integration in a telecare framework. The integrated voice and touch interaction with the avatar 'Addison' should also contribute to improve the human-computer interaction.

Limitations

Possible limitations of the pilot study are the lack of results on usability or acceptance of the US American version of Addison Care that we can refer to. Cultural adaption and translation into German therefore might not be the only reason for a suboptimal user experience. Interviews allow to gain insight into this issue. The effectiveness of the extensive data collection process has to be proven as

well as the recruitment process. The highly selective sample of the pilot study will diminish ethnical or socio-economic diversity which will be introduced thoroughly in the study following the pilot. Within the qualitative branch of the mixed-methods study we seek sufficient richness of data but do not expect to achieve a data saturation. The study´s time line may be influenced by COVID-19 pandemic recruitment-wise as well as by pandemic regulations in Germany which cannot be foreseen at the current situation. Because we do not have an influence on the stability of the Internet connection, this could be another source of uncertainty. Finally, it is not the aim of the pilot study to show effects on the health status of the users. But the multiple instruments for testing health status-associated phenomena should provide adequacy to show such effects in a subsequent main study.

Contributors

SK, NaS, JD, PK, NN, JO, ES, SP, MB, MK, REM and BM participated in the design of the study protocol. SK, NaS, PK, JD, TK, and ES drafted the protocol manuscript. MB, BH, BM, SP, AW, DL, AvZ and JO critically revised and commented on its previous versions and the final version. All authors critically reviewed the manuscript and agreed on submission.

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Declarations

The study protocol has been approved by the ethic committee of the German Society for Nursing Science (21-037) and is registered in the German Clinical Trials Register (ID: DRKS0002599).

Conflict of interest

ES, BH, and MB are employees of Electronic Caregiver, Las Cruces, New Mexico, United States

Figure legend

Figure 1 Addison Care functions in German version (Reproduced with permission from https://electroniccaregiver.com)

Figure 2 Study flow, phenomenon of interest, instruments, data sets, and settings

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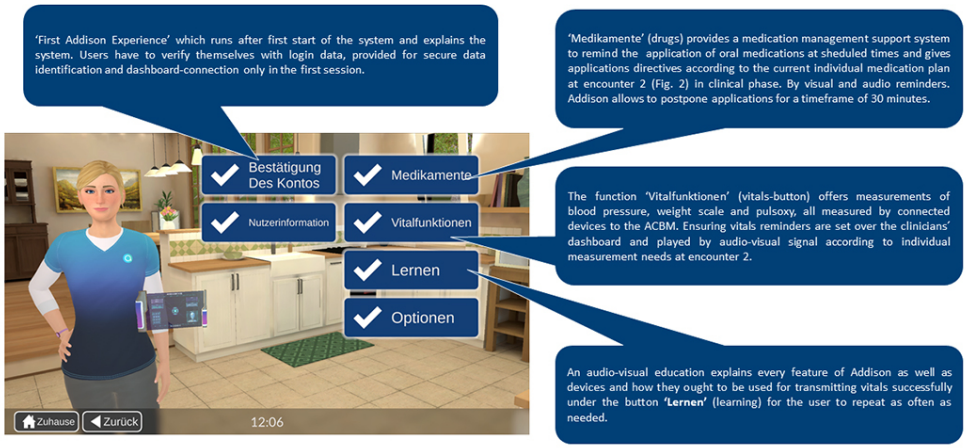
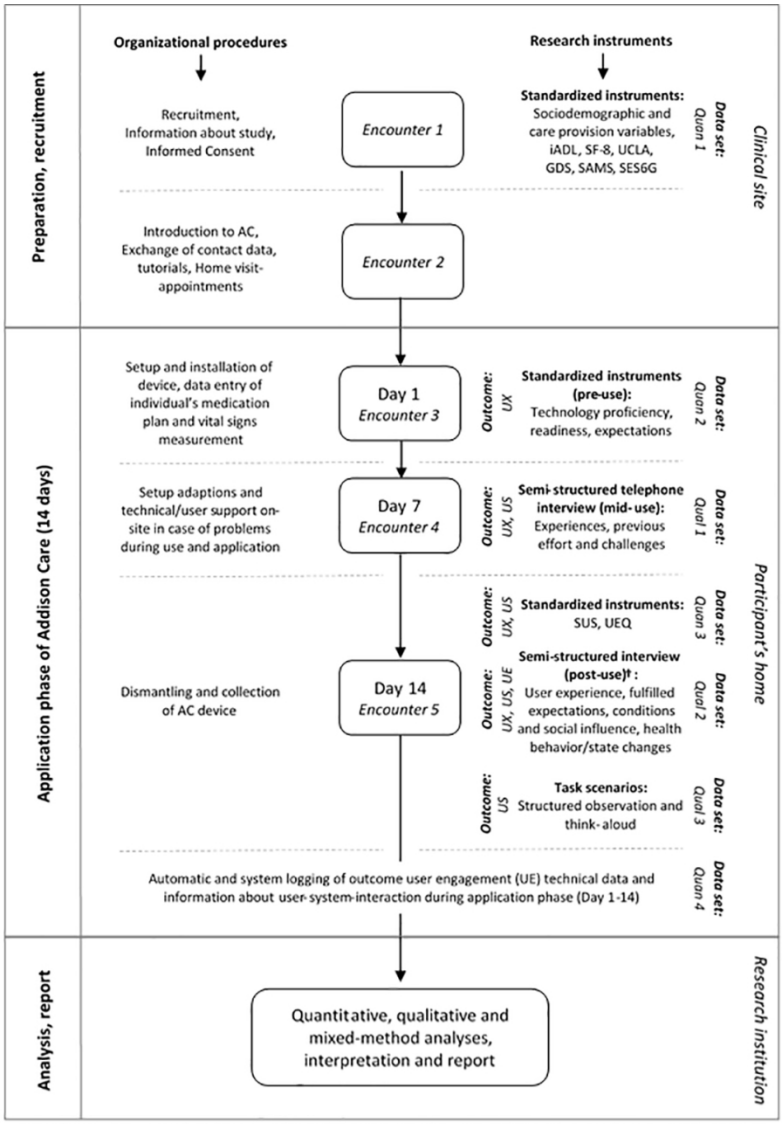


Figure 1: Addison Care functions in German version (Figure 1 reproduced with permission from https://electroniccaregiver.com)

90x50mm (300 x 300 DPI)



Notes: † in case of the presence of relatives: semi-structured interview with relatives about their impressions and experiences towards AC; AC Addison Care, GDS Geriatric Depression Scale, iADL Instrumental Activities of Daily Living Scale, SAMS Stendal Adherence with Medication Score, SES6G Self-Efficacy for Managing Chronic Disease 6-item Scale, SF-8 Health Related Quality of Life Short-Form-8-Questionnaire, SUS System Usability Scale, UCLA University of California Los Angeles Loneliness Scale, UE User Engagement, UEQ User Experience Questionnaire, US Usability, UX User Experience

Figure 2: Study flow, phenomenon of interest, instruments, data sets, and settings

90x138mm (300 x 300 DPI)

Supplement 1: SPIRIT Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Protocol adherence: addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Y:01
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Y:02
	2b	All items from the World Health Organization Trial Registration Data Set	Y
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	Y:16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Y:01, 16
	5b	Name and contact information for the trial sponsor	Y:16
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Y:16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Y:09, 13
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Y:03-06, 08
	6b	Explanation for choice of comparators	NA
Objectives	7	Specific objectives or hypotheses	Y:08
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Y:08
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Y:09, Figure 2
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Y:09
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Y:07-08, Figure 2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Y:13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Y:09-11, Figure 2
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Y:10

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Y:09, Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Y:09
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Y:09
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Y:10-13

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Y
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Y: 12-13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Y: 14-15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	X
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	X
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	X
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Y: 13
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Y: 13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	X
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Y: 14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Y: 14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Y: 09
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Y: 13-15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Y: 16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Y: 15
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	X
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	X

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

1. Informed Consent

Patient Consent Form

Name of patient in block letters: .....

Date of birth: .....

I agree to participate in the patient survey and use of the digital support platform "Addison Care" in the project PiloTT-A: Piloting of the virtual telecare technology "Addison".

I have been informed that I can decline to participate without any adverse consequences, especially regarding my medical care.

The Paracelsus Medical Private University Salzburg (Austria) is responsible for conducting the survey in the context of using "Addison Care" as a digital support service for medical care needs.

I have been informed by Mr./Mrs. ..... in a detailed conversation about the nature, type, scope and significance of the survey, as well as the aims of using the Addison Care platform, and have received a copy of this consent form.

It has been explained to me for what purpose, to what extent, on what legal basis and for how long my data from the survey will be stored and what rights I have towards the responsible party with regard to my personal data. I have received a corresponding data protection declaration as well as an information letter.

Furthermore, I agree that the clinic's physicians will hand over my current list of medications to a member of the project team.

In addition, I have been informed that by using the Addison Care platform, my usage behavior of this technology will be transmitted to the Paracelsus Medical Private University, based on data known to me.

Furthermore, I have read the text of this patient information and consent form, which comprises a total of 9 pages. I have had sufficient time to decide. I have no further questions at this time.

I am aware that my participation in the project is voluntary and that I can revoke it at any time without giving reasons and without personal disadvantage for further medical and nursing treatment. In this case, the collected data will be completely deleted and I will be informed about it.

I declare that I am willing to participate in the research project and consent to the associated processing of my personal data and the usage data of the Addison Care platform, which are known to me.

I consent to the processing of my data collected as part of this clinical trial and as described in the "Data Protection" section of this document.

Insofar as special personal data within the meaning of Art. 9 DSGVO, such as health data, are collected, my consent also relates to this information.

I hereby declare my voluntary participation in the survey.

I consent that any personal information I provide for the survey may be stored and scientifically processed by the Paracelsus Medical Private University Salzburg.

My personal information will only be used for this research project. Once the survey has been completed, it will no longer be possible to make any further link to me as a person.

_____	_____
Date	Patient's signature
_____	_____
Date	Surname, first name of the informing staff member

Ethikkommission der DGP • Stockumer Straße 12 • 58453 Witten

Paracelsus Medizinische Privatuniversität
Herrn Univ.-Prof. Dr. Dr. h.c. Jürgen Osterbrink
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für Pflegewissenschaft
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Vorsitz Prof. Dr. Sabine Bartholomeyczik
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58453 Witten

Ethikkommission@dg-pflegewissenschaft.de

Your proposal no. 21-037 to the ethical review committee of the German Society of Nursing Science (EK-DGP)

Dear Mr. Osterbrink,

the EK-DGP discussed and evaluated your proposal

A pilot study of Addison Care, the Virtual Telecare Technology, - PiloTT-A (application no. 21-037)

submitted 2021-11-16.

The committee decided to give you an ethical approval.

Good luck for the project!

2021-12-27

Prof. Dr. Sabine Bartholomeyczik
Chairperson EK-DGP

BMJ Open

Piloting of the virtual telecare technology 'Addison Care' to promote self-management in persons with chronic diseases in a community setting: protocol for a mixed methods user experience, user engagement and usability pilot study

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Primary Subject Heading:	Nursing
Secondary Subject Heading:	Health services research

Keywords:	PRIMARY CARE, PREVENTIVE MEDICINE, GERIATRIC MEDICINE

Piloting of the virtual telecare technology 'Addison Care' to promote self-management in persons with chronic diseases in a community setting: protocol for a mixed methods user experience, user engagement and usability pilot study

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Word Count: 4.148

ABSTRACT (293 words)

Introduction: Chronic diseases in older adults are one of the major epidemiological challenges of current times and leading cause of disability, poor quality of life, high health care costs, and death. Self-management of chronic diseases is essential to improve health behaviors and health outcomes. Technology-assisted interventions have shown to improve self-management of chronic diseases. Virtual avatars can be a key factor for the acceptance of these technologies. Addison Care is a home-based telecare solution equipped with a virtual avatar named Addison, connecting older persons with their caregivers via an easy-to-use technology. A central advantage is that Addison care provides access to self-management support for an up-to-now highly underrepresented population - older persons with chronic disease(s), which enables them to profit from e-health in everyday life.

Methods and analysis: A pragmatic, non-randomized, one-arm pilot study applying an embedded mixed-methods approach will be conducted to examine user experience, usability, and user engagement of the virtual avatar Addison. Participants will be at least 65 years old and will be recruited between September 2022 and November 2022 from hospitals during the discharge process to home care. Standardized instruments, namely the User Experience Questionnaire (UEQ), System Usability Scale (SUS), Instrumental Activities of Daily Living (iADL) scale, Short-Form-8-Questionnaire (SF-8), UCLA Loneliness Scale, Geriatric Depression Scale (GDS), Stendal Adherence with Medication Score (SAMS) and Self-Efficacy for Managing Chronic Diseases Scale (SESG6), as well as survey-based assessments, semi-structured interviews and think-aloud protocols will be used. The study seeks to enroll 20 patients that meet the criteria.

Ethics and dissemination: The study protocol has been approved by the ethic committee of the German Society for Nursing Science (21-037). The results are intended to be published in peer-reviewed journals and disseminated through conference papers.

Trial registration number: German Clinical Trials Register (ID: DRKS00025992).

Keywords: Telecare, virtual avatar, older people, chronic disease self-management, pilot study, user experience, e-health;

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This pilot study provides an opportunity to explore the acceptability of and experiences with a potentially beneficial e-health technology in the underrepresented population of chronically ill older persons in a telecare setting.
- The mixed-methods study design will provide a deep and broad insight on usability, user experience and user engagement of Addison care as a German-speaking, culturally adapted virtual avatar.
- This investigation evaluates the efficacy of a sophisticated virtual avatar, Addison, in assisting with many crucial health management tasks – including medication management and health vitals monitoring.
- A focus on barriers to user-engagement for those who are technologically hesitant will provide rich information concerning how best to design virtual avatars and e-health technologies to match user needs and mental models.
- The primary limitation of this study is the relatively small sample size due to our selective inclusion criteria, which may diminish the ethnic and socio-economic diversity of our sample.

BACKGROUND

Societies across the globe are facing a significant shift in age demographics whereby older adults are becoming an increasingly larger group within their population. This phenomenon is one of the most salient economic, social, and medical issues of current times.[1] Aging increases both the risk for most chronic diseases and for multimorbidity. Between 34% and 61% of older adults are multimorbid [2],

which can have consequences such as disability and functional decline, poor quality of life, social isolation, depression, and high health care costs.[3, 4]

Patients themselves have an integral role in the management of their chronic disease.[5] Factors that influence effective self-management of chronic disease include: experience, skill, motivation, culture, confidence, habits, physical and mental function, social support, and access to care.[6]

Self-management of chronic diseases is defined as the response to signs and symptoms when they occur, with the goal that patients play an active role in optimising health outcomes and minimizing the impact of their conditions.[6] Self-management support refers to patient, healthcare professional, and healthcare system interventions aimed to improve self-management behaviours.[7] Self-monitoring vitals [8] and medication adherence have been recognized as two of the most essential self-management activities performed by patients to promote their health.[9]

Although interventions designed to promote self-management in chronic diseases have traditionally been offered in-person, delivering these interventions remotely utilizing available technology (e.g., mobile smart phones, Internet, interactive voice response, telephone, virtual reality) has become more prevalent.[10] These technology-assisted interventions have shown to improve self-management and health status.[11, 12]

Digital information technologies support people with care requirements to maintain their independence, improve quality of life, increase health literacy and aid caregivers in their duties.[13, 14] Telehealth is one of the fastest-growing sectors in health care. The term refers to a broad array of provider-to-patient communication and has been defined as using telecommunications, information technologies, and devices to share information and to provide clinical, population health, and administrative services at a distance.[15] Remote patient monitoring is a widely used telehealth intervention that can effectively support self-management in patients with chronic diseases.[7]

Remote Patient Monitoring

Remote Patient Monitoring (RPM) is a promising solution for facilitating the patient-physician relationship while addressing the shortage of healthcare workers today.

Studies concerning the efficacy of RPM has spanned the topics of post-operative rehospitalization, chronic disease management, medication adherence, and quality of life and has shown promising results.[16-20] However, RPM technology can only benefit patients who choose to actively interact with the devices. As compared to younger users, elderly users also face unique challenges that are a direct result of aging – such as declines in dexterity, hearing, and vision. As a result, researchers have identified that improving ease of navigation for task completion, ensuring appropriate size and color of font, and properly configuring the size of the hardware itself are paramount in addressing technological hesitancy.[21]

Virtual Avatars

Graphic user interfaces, which can improve the user experience and personalize the experience for the user through virtual avatars, have begun to be incorporated into RPM systems. Virtual avatars are an emerging feature in RPM that has shown propitious results in terms of user engagement, health education, and self-care behavior.[22]

One important factor in the receptiveness of patients to virtual avatars is the avatar's appearance. Bott [23] investigated the impact of a virtual pet avatar to deliver surveys to older clients. They found that those who interacted with the avatar experienced lower rates of delirium, fewer falls, and decreased loneliness. However, research has generally shown that anthropomorphic characteristics are often preferable for virtual healthcare avatars [24] – as well as similarities in appearance between the avatar and the user.[25] Previous literature has revealed that when designing virtual agents for older persons, key factors related to acceptance of technology include conversational latency, gamification, and artificially intelligent lexicon.[26]

User experience and technology acceptance among older persons

Understanding how older adults perceive technology and virtual avatars may lead to improvements in the accessibility, acceptability, and adoption of virtual avatars among older persons with chronic diseases. This can be accomplished through user experience (UX) research, wherein the overall experience of the user is assessed through measures related to usability, user engagement, usefulness, function, credibility, and satisfaction with the technology.[27] While behavior, cognition, and affect are important defining components of user engagement [28], learnability, efficiency, memorability, few errors and satisfaction are defining components of usability.[29] UX is based upon User-Centered Design (UCD), wherein the needs and characteristics of the end user become the focus of technology design and development, with the intention of higher acceptance and fewer user errors.[30]

Theories that predict and explain health technology acceptance and use can help to tailor the technology to specific patient needs. One of the more recent models, the Unified Theory of Acceptance and Use of Technology (UTAUT) [31], posits that a person's intent to use [acceptance of technology) and usage behavior (actual use) of a technology is predicated by the patient's performance and effort expectancy of the technology. The UTAUT also suggests social influence and facilitating conditions as determinants of behavioral intention to use the technology.[31, 32] Most older persons are significantly less adept at technology use than the general population, with technology anxiety being a major influence on older users' intent to use technologies.[33] However, older adults are interested in integrating new technologies into their healthcare.[34] Studies confirm the applicability of the UTAUT in the context of Telecare services among older persons.[35]

Intervention: Addison Care Tablet Personal Computer (PC)

The present research pilots an intervention provided by Addison Care [36], which is an innovative home-bound connected virtual RPM platform for individuals living with chronic disease. A 3D-animated nurse named 'Addison' is the center of interaction between the system and its users, personifying the telehealth experience for the user. The pilot study encompasses two health-related functions of Addison Care: 'Addison' supporting the user in self-monitoring relevant vitals (blood

pressure, weight, pulse and oxygen saturation) as well as medication schedule adherence. This is achieved by offering reminder and monitoring functionalities (see Fig. 1).

[Figure 1 about here]

The Addison Care hardware consists of a tablet PC with a speaker, a microphone module, and a touch screen (see Figure 1). The tablet connects with Bluetooth vitals measuring devices and can be installed in a user's home. Avatar technology combined with natural language understanding and automatic speech recognition provides users with effective natural interaction with the assisting technology.[22, 26] Subtitles, vital signs, and medications are graphically illustrated on the Addison Care interface for clear communication between the virtual agent and the user.

The Addison Tablet PC is connected to a web-based dashboard that allows access to user data, including vitals measurements and medication reminders. For the pilot study, medication plans, reminder-options, and contact information are managed by members of the study team, who also act as a support team for the technical set-up and in case of technical problems. The intervention in this study involves voice-driven audio-centered interaction between Addison and users in German, as well as the implementation of a German touch screen interface. Introduction of Addison Care to German users requires adaption of the original technology to ensure a good cultural fit. Adaptations were made to the surroundings of the avatar, as well as to Addison's mannerisms. Additionally, changes were made to the system to ensure a good fit between system and real life in terms of interactive elements [from basics ensuring appropriate data and time formats to more complex elements like making sure the avatar interacts in a culturally appropriate manner with the user). Voice and touch interaction modes are currently adapted from English into German. All piloted features of Addison Care are shown in Fig. 1.

Objectives

While other studies have provided insight into the potential of digital health technology and virtual avatars, the vast majority have been tested within laboratory settings, where older adults were unable to interact with the technology in a natural environment. Additionally, the digital health systems and virtual avatars were not culturally adapted after development.

The study aims to explore the feasibility, acceptability, experience, engagement, and usability of the culturally tailored health technology and the virtual avatar Addison for self-management for older patients with chronic diseases in their own home.

METHODS AND ANALYSIS

A pragmatic, non-randomized, one-arm pilot study applying an embedded mixed-methods approach will be conducted to examine the primary outcomes 'user experience', 'usability', and 'user engagement' of the virtual avatar Addison three times within the use span. 'Embedded' refers to the integration of qualitative methods into a quantitative methodology framework, or vice versa, to provide enriched insights or understanding into the phenomena of interest.[31, 37] The study design is pluralistic, problem-centered, real-world applicable, and focused on the consequences of actions, stemming from pragmatism as a research paradigm.[37] The present protocol followed the SPIRIT guidelines (see Supplementary 1).[38] Data collection will take place between September 2022 and November 2022.

Recruitment criteria and process

Eligible patients will be identified by medical specialists in in German hospitals. The inclusion criteria are as follows:

- Planned patients transition from hospital to extramural care
- Three to nine drugs (regular intake of drugs, no status of hypermedication)
- 65 years or older with a chronic health condition
- Ability to speak and understand German language

The exclusion criteria are:

- Ten or more drugs per day
- Younger than 65 years old
- Moderate to severe cognitive impairment or severe psychiatric disorders

Provided that these criteria are met and general interest in using health technology is expressed, information about the pilot study and the intervention will be shared. If a patient declares the will to participate, a meeting with the support team will be arranged while the patient is still at the hospital. Potential participants will be informed of all aspects of the study through verbal instruction and written materials (Figure 2, Encounter 1). After written informed consent (see Supplementary 2) is provided, living situation and socio-demographic data will be assessed by research assistants.

Setting and sample size

Addison Care will be piloted in participants´ homes, located in a community setting, after their discharge from hospital for two consecutive weeks. In Encounter 2 (see Figure 2) within 1 day after the informed consent is provided, the support team will give first instructions on Addison Care while the participant is still hospitalized. First adjustments of reminder, medication plan, and vital measurements will be provisioned for the use of Addison Tablet PC at home. This study seeks to enroll 20 patients. The sample size is an adequate number to evaluate study feasibility, test the study procedures and explore the user experience.[39, 40]

Patient and public involvement

In advance of the pilot study, older adults assisted in the development of the data collection materials and pre-testing of Addison Care. However, patients and the public were not involved in the development of the research question, outcome measures and the design of the study.

Outcomes, Instruments, and Variables

Building upon the theoretical concepts of technology acceptance (UTAUT), we will assess user experience, usability, and user engagement (primary outcomes), as well as participant background information (e.g., sociodemographic, care provision) and health status-associated phenomena (functional status, quality of life and wellbeing, loneliness, depression, medication adherence, and self-management) using standardized, quantitative and semi-standardized qualitative research instruments (see Figure 2).

Standardized research instruments

User experience. The German version of the User Experience Questionnaire (UEQ) [41] will be used to assess user experience. The UEQ consists of 26 items along six scales: attractiveness (6 items, Cronbach's alpha α=0.89), perspicuity (4 items, α=0.82), efficiency (4 items, α =0.73), dependability (4 items, α=0.65), stimulation (4 items, α=0.76), and novelty (4 items, α=0.83).[41, 42] Each item represents a 7-point rating scale (-3 most negative rating, +3 most positive rating) of properties that the product under study may have. An average score is computed for each scale.

Usability. To assess the usability of Addison Care, the validated German version of the System Usability Scale (SUS) will be applied.[43] The SUS [44] consists of 10 items and is a standardized, generic instrument for assessing the usability of technical applications, mobile applications, or devices. Internal consistency has been reported to range between α =0.70 to 0.95.[45] The SUS consists of 10 items, each with five-point rating scales (1-strongly disagree to 5-strongly agree). The standardized scoring of the SUS results in a total score between 0 to 100 points using a given norm-based scoring algorithm.[45]

User engagement. Automatic system and data logging information will be used to measure user engagement in terms of intensity and type of interactions between users and Addison Care. This non-participatory data collection, e.g., documenting data using automatically protocolled technical variables without having asked questions or the presence of an observer, will provide essential

information on the actual use, used functions, and user engagement with certain contents of the product of interest.[46-48]

Functional status. The German translation [49] of the Instrumental Activities of Daily Living (iADL) scale [50] will be applied to assess patients' functional status in terms of activities of daily living. The iADL is a standardized instrument that measures functionality related to eight domains of daily living. It has reported reliability coefficients ranging from 0.85 to 0.91.[51] Each domain is measured using either three or four ability levels with 0 or 1 point per domain, resulting in a summary score of 8 points at maximum. Due to a strong reference of some items to household aspects, gender-specific scores will be used, e.g., 0 (low function, dependent) to 8 (high function, independent) for women and 0 to 5 for men, respectively.[51]

Quality of life. Health-related quality of life will be measured by the German version of the Short-Form-8-Questionnaire (SF-8).[52] The SF-8 assesses the 8 dimensions physical functioning, role physical (role limitations because of physical health), bodily pain, general health, vitality, social functioning, role emotional (role limitations because of emotional problems), and mental health, by one item each, and along two scales 'physical component summary score' and 'mental component summary score'. The items comprise of five- or six-point response scales that verbalize the extent to which each dimension is present. In addition to single-item analysis, the two summary scores will be measured using a given norm-based scoring method. Next to an adequate test-retest reliability [52], an overall internal consistency between α=0.86 and 0.92 have been reported.[53]

Loneliness. To assess participants' perception of social isolation and loneliness, the shortened, 3-item German version [54, 55] of the UCLA (University of California, Los Angeles) Loneliness Scale will be applied. Each item exhibits a five-level response scale (very often, often, sometimes, rarely, never) and will be analysed item-by-item. Cronbach's alpha for the 3-item loneliness scale was 0.72.[54]

Depression. The German translation [56] of the Geriatric Depression Scale (GDS) will be used to evaluate the presence of depression.[57, 58] The 8-item version will be applied to make the survey as

time-efficient as possible.[59] Participants are asked about selected symptoms of depressive states over the past week using a dichotomous response format (no vs. yes). The total sum score of the GDS-8 is 0-8 points. Internal consistency with α>0.80 has been shown [59]. A recommended cut-off score of GDS≥3 indicating relevant indications of depression will be applied.

Medication adherence. Participants' adherence to their medication regimen will be measured by the Stendal Adherence with Medication Score (SAMS).[60] SAMS consists of 18 items on a five-level response scale (0-4) assessing fully adherent to nonadherent medication behaviour per item.[61] Responses are summarized into a cumulative point scale (0-72), which can be categorized as fully adherent (0), moderately adherent (1-10), and not adherent (>10). An overall internal consistency of α=0.83 has been reported.[61]

Self-management. To assess participant´s Self-Efficacy for Managing Chronic Diseases (SESG6), the German version of the 6-item scale will be used.[62] The six items are rated with a 10-level Likert-type scale (1 'not at all confident' to 10 'totally confident'). A mean score over at least four of the six items will be calculated, thus allowing a maximum of two missing item responses. SESG6 has been attested a high internal consistency measure of α =0.93.[62]

Technology proficiency, readiness, and expectations. A standardized face-to-face interview prior to the use of Addison Care ('pre-use interview') will be performed to collect information on participant technology proficiency and readiness (7 items) in terms of experience with and use of general information and communication technologies (3 items) as well as expectations regarding the upcoming use of the Addison Care technology (6 items). These closed-ended questions were derived from empirical and theoretical literature [31, 32, 63] and further adapted by the research team.

Sociodemographic and care provision variables. Sociodemographic and care-relevant variables will be collected by means of a short, standardized 9-item questionnaire. Age of participants, gender, living situation, place of residence in terms of urbanization, care provision by relatives, and care provision by ambulant/mobile care service will be assessed using closed-ended questions. Information on

documented primary diagnoses and existing additional chronic diseases will be collected using open-ended questions and categorized applying the 11th revision of the International Classification of Diseases and Related Health Problems (ICD-11).[64]

Semi-standardized research instruments

First experiences and encountered technical obstacles. A qualitative, semi-structured brief telephone interview ('mid-use interview') with users after one week of Addison interaction will be conducted. Information about users' experiences to date, as well as previous effort and encountered challenges in using the Addison Care technology will be collected. The user reports are to be recorded in an open-ended documentation sheet.

User experience, fulfilled expectations, perceived enabling conditions for use and technology's social influence, and health behaviour. A comprehensive qualitative, semi-structured, face-to-face interview will explore participants' perspectives with reference to the fulfilled expectations after the use of Addison Care ('post-use interview'), perceived enabling conditions, and social influence in the use of the technology, as well as the participant's experiences and adaptions of health behaviour. The interview guide questions on user experience are based on the respective literature on UX research [65], those on conditions and technology's social influence along the main factors of the UTAUT model [31, 32], and those on health behaviours were developed against the background of the Health Action Process Approach (HAPA).[66] The interview will be audio-recorded and transcribed. With reference to the embedded mixed-methods approach, the four most striking individual ratings of the previously collected standardized User Experience Questionnaire (UEQ) will be thematised and perceived changes in secondary outcomes (functional status, quality of life, loneliness, depression, medication adherence) will be assessed using open-ended questions. To address their perspectives on the use of Addison Care, an optional topical block of guided questions will be operationalized.

Task performance scenario and think-aloud protocol. Finally, to gain insight into user thoughts, decision-making processes, and how they experience the Addison Care technology, a structured

observation with an accompanying think-aloud protocol will be applied.[67] Participants will be asked to perform a set of specific tasks with Addison Care while verbally expressing their immediate thoughts, and explaining their reactions during system interaction. Task performance and participant comments will be documented using a structured observation sheet.

[Figure 2 about here]

User safety and data management

During the two weeks study period, medical emergencies, acute deterioration in health or care needs, patients' feelings of insecurity, or hospital admissions will constitute reasons to end the participation early. Formal health services in the community setting will be informed about the use of Addison Care by their clients. Informal caregivers of the participants will be educated about Addison Care and are instructed to contact the support team in need of help (see Figure 2).

Figure 2 provides detailed information on the different data retrieved during participants´ enrolment. Personal information of participants will be accessed by the support team only, who will monitor the dashboard and assist with any user problems. Dashboard access is granted by login data provided by Addison Care USA.

All data retrieved empirically (see figure 2) will be saved on study-specific computers during data collection and stored in password-protected folders on the support team storage after completed data collection. User engagement data will be stored on Addison Tablet PC for short periods of time being but regularly exported onto the server from the clinical dashboard and after the end of the pilot study transferred to study-specific computers. All personal data will be stored at a server in Berlin in Germany and encrypted. According to European Union General Data Protection Regulations, participants have the right to view all stored data or choose to delete their data at any given time as long as their data has not been anonymized by code yet.

Analysis

Various data will be organized and triangulated in data sets Quan 1-4 and Qual 1-3 (see Figure 2) for analysis that fit the relevant phenomenon of interest. Final integration of overall results will take place upon conclusion of the study [37] and will be summarized with a joint display by using a mixed methods matrix.[68]

Participants` characteristics will be statistically described using information on socio-demographics, living and care provision, quality of life, health literacy, activities of daily living, and medication adherence (Quan 1, Figure 2).

A thematic content analysis of the qualitative data gained from interviews and observations in encounters 4 and 5 (see Figure 2) will be performed, expanding the deductively developed code by inductive inputs.[69] Deductive codes prepared from theoretical pre-considerations will include the concepts of user experience as well as usability. Coding strategy will separate the two phenomena during the coding process. User experience results will be produced by triangulating the results of the User Experience Questionnaire (Quan 3) as well as code system elements gathered in qualitative data sets (Qual 1, 2, 3). These three data sets will provide usability results after interviews are transcribed and coded. The codes will then be merged with the SUS results (Quan 3) to get a clear picture of obstacles and acceptance. User Engagement data will track usage events like logins, reminders, and overall Addison-user-interaction over the 2-week usage period - resulting in data set Quan 4 (see Figure 2). To facilitate the subsequent main study, deductive codes for the area of a feasibility study are also included in the coding strategy.[70] All quantitative data will be analyzed using common descriptive statistics.

Ethics and dissemination

Ethical considerations

This pilot study was approved by the ethics committee of the German Society for Nursing Science (21-037) to ensure that the research is done in accordance with the Declaration of Helsinki and in line with

the current legislation authority (see Supplementary 3). The pilot study is registered in the German Clinical Trials Register (ID: DRKS00025992).

Dissemination

The results are intended to be published in peer-reviewed journals and disseminated through conference papers.

Overview

This protocol presents research that assesses the feasibility, acceptability, experience, engagement, and usability of Addison Care – a health technology and virtual avatar for older persons with chronic diseases in their own home.

For this purpose, we culturally adopted the Addison Care technology and its functions (tutorial, medication management, testing vital signs) to explore participants' acceptance and experiences of the health technology and the virtual avatar.

For older adults with chronic diseases, the overarching goal of self-management is to enhance their quality of life and maintain independence, all while supporting formal and informal caregivers.

The goal of this pilot study is to further our understanding of the potential issues and challenges that will be used as the foundations for a larger randomized control study.

One of the strengths of this study is the use of the health technology for a longer period of time and with real patients in a natural setting. Another strength lies in the cultural adaption of the health technology and its integration in a telecare framework. The integrated voice and touch interaction with the avatar 'Addison' should also contribute to improve the human-computer interaction.

Limitations

Possible limitations of the pilot study are the lack of results on usability or acceptance of the US American version of Addison Care that we can refer to. Cultural adaption and translation into German therefore might not be the only reason for a suboptimal user experience. Interviews allow to gain insight into this issue. The effectiveness of the extensive data collection process has to be proven as well as the recruitment process. The highly selective sample of the pilot study will diminish ethnical or socio-economic diversity which will be introduced thoroughly in the study following the pilot. Within the qualitative branch of the mixed-methods study we seek sufficient richness of data but do not expect to achieve a data saturation. The study´s time line may be influenced by COVID-19 pandemic recruitment-wise as well as by pandemic regulations in Germany which cannot be foreseen at the current situation. Because we do not have an influence on the stability of the Internet connection, this could be another source of uncertainty. Finally, it is not the aim of the pilot study to show effects on the health status of the users. But the multiple instruments for testing health status-associated phenomena should provide adequacy to show such effects in a subsequent main study.

Contributors

SK, NaS, JD, PK, NN, JO, ES, SP, MB, MK, REM and BM participated in the design of the study protocol. SK, NaS, PK, JD, TK, and ES drafted the protocol manuscript. MB, BH, BM, SP, AW, DL, AvZ and JO critically revised and commented on its previous versions and the final version. All authors critically reviewed the manuscript and agreed on submission.

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Declarations

The study protocol has been approved by the ethic committee of the German Society for Nursing Science (21-037) and is registered in the German Clinical Trials Register (ID: DRKS0002599).

Conflict of interest

ES, BH, and MB are employees of Electronic Caregiver, Las Cruces, New Mexico, United States

Figure legend

Figure 1 Addison Care functions in German version (Reproduced with permission from https://electroniccaregiver.com)

Figure 2 Study flow, phenomenon of interest, instruments, data sets, and settings

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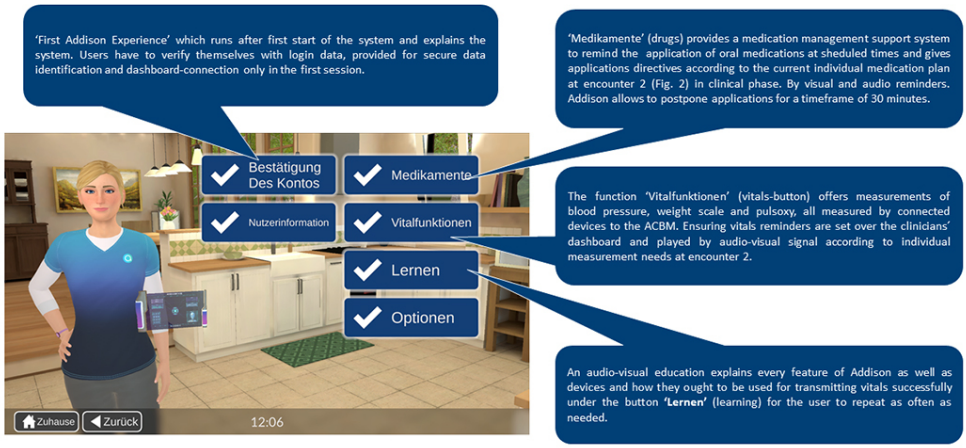
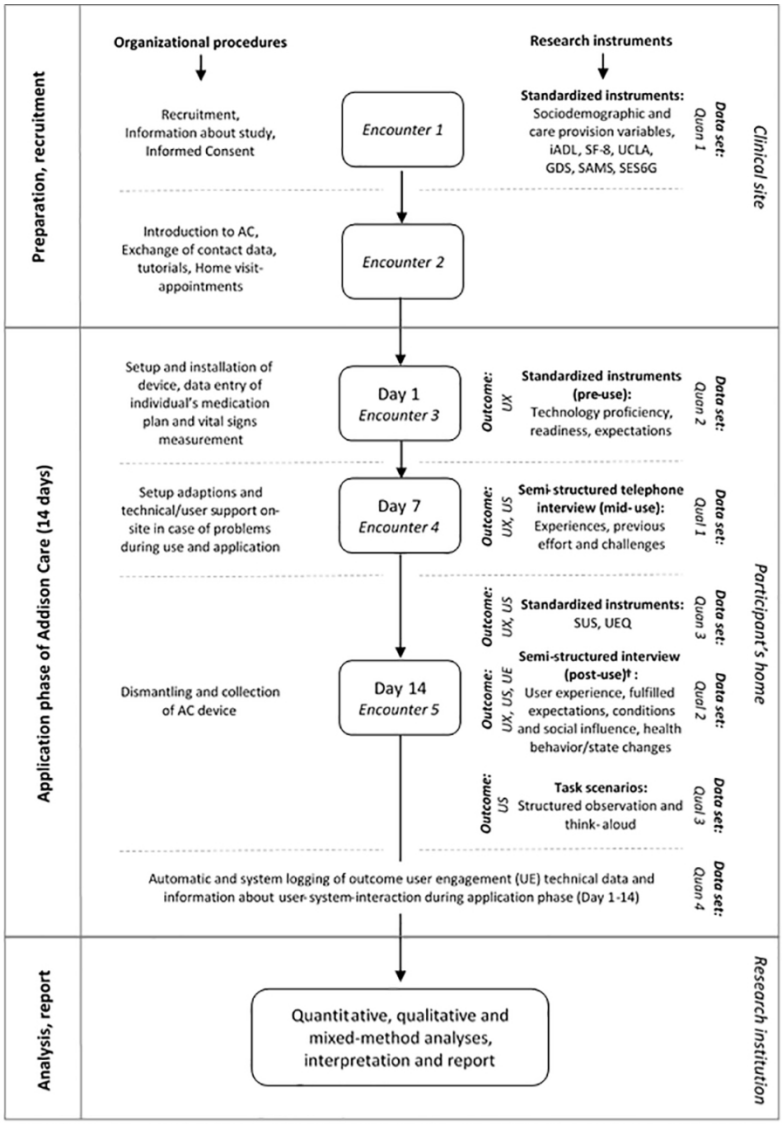


Figure 1: Addison Care functions in German version (Figure 1 reproduced with permission from https://electroniccaregiver.com)

90x50mm (300 x 300 DPI)



Notes: † in case of the presence of relatives: semi-structured interview with relatives about their impressions and experiences towards AC; AC Addison Care, GDS Geriatric Depression Scale, iADL Instrumental Activities of Daily Living Scale, SAMS Stendal Adherence with Medication Score, SES6G Self-Efficacy for Managing Chronic Disease 6-item Scale, SF-8 Health Related Quality of Life Short-Form-8-Questionnaire, SUS System Usability Scale, UCLA University of California Los Angeles Loneliness Scale, UE User Engagement, UEQ User Experience Questionnaire, US Usability, UX User Experience

Figure 2: Study flow, phenomenon of interest, instruments, data sets, and settings

90x138mm (300 x 300 DPI)

Supplement 1: SPIRIT Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Protocol adherence: addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Y:01
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Y:02
	2b	All items from the World Health Organization Trial Registration Data Set	Y
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	Y:16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Y:01, 16
	5b	Name and contact information for the trial sponsor	Y:16
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Y:16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Y:09, 13
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Y:03-06, 08
	6b	Explanation for choice of comparators	NA
Objectives	7	Specific objectives or hypotheses	Y:08
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Y:08
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Y:09, Figure 2
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Y:09
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Y:07-08, Figure 2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Y:13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Y:09-11, Figure 2
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Y:10

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Y:09, Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Y:09
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Y:09
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	NA
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	NA
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Y:10-13

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Y
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Y: 12-13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Y: 14-15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	X
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	X
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	X
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Y: 13
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Y: 13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	X
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Y: 14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Y: 14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Y: 09
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Y: 13-15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Y: 16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Y: 15
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	X
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	X

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

1. Informed Consent

Patient Consent Form

Name of patient in block letters: .....

Date of birth: .....

I agree to participate in the patient survey and use of the digital support platform "Addison Care" in the project PiloTT-A: Piloting of the virtual telecare technology "Addison".

I have been informed that I can decline to participate without any adverse consequences, especially regarding my medical care.

The Paracelsus Medical Private University Salzburg (Austria) is responsible for conducting the survey in the context of using "Addison Care" as a digital support service for medical care needs.

I have been informed by Mr./Mrs. ..... in a detailed conversation about the nature, type, scope and significance of the survey, as well as the aims of using the Addison Care platform, and have received a copy of this consent form.

It has been explained to me for what purpose, to what extent, on what legal basis and for how long my data from the survey will be stored and what rights I have towards the responsible party with regard to my personal data. I have received a corresponding data protection declaration as well as an information letter.

Furthermore, I agree that the clinic's physicians will hand over my current list of medications to a member of the project team.

In addition, I have been informed that by using the Addison Care platform, my usage behavior of this technology will be transmitted to the Paracelsus Medical Private University, based on data known to me.

Furthermore, I have read the text of this patient information and consent form, which comprises a total of 9 pages. I have had sufficient time to decide. I have no further questions at this time.

I am aware that my participation in the project is voluntary and that I can revoke it at any time without giving reasons and without personal disadvantage for further medical and nursing treatment. In this case, the collected data will be completely deleted and I will be informed about it.

I declare that I am willing to participate in the research project and consent to the associated processing of my personal data and the usage data of the Addison Care platform, which are known to me.

I consent to the processing of my data collected as part of this clinical trial and as described in the "Data Protection" section of this document.

Insofar as special personal data within the meaning of Art. 9 DSGVO, such as health data, are collected, my consent also relates to this information.

I hereby declare my voluntary participation in the survey.

I consent that any personal information I provide for the survey may be stored and scientifically processed by the Paracelsus Medical Private University Salzburg.

My personal information will only be used for this research project. Once the survey has been completed, it will no longer be possible to make any further link to me as a person.

_____	_____
Date	Patient's signature
_____	_____
Date	Surname, first name of the informing staff member

Ethikkommission der DGP • Stockumer Straße 12 • 58453 Witten

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Ethikkommission@dg-pflegewissenschaft.de

Your proposal no. 21-037 to the ethical review committee of the German Society of Nursing Science (EK-DGP)

Dear Mr. Osterbrink,

the EK-DGP discussed and evaluated your proposal

A pilot study of Addison Care, the Virtual Telecare Technology, - PiloTT-A (application no. 21-037)

submitted 2021-11-16.

The committee decided to give you an ethical approval.

Good luck for the project!

2021-12-27

Prof. Dr. Sabine Bartholomeyczik
Chairperson EK-DGP