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PROTOCOL

Proactive Monitoring of Chronic Conditions Using WMDs in Primary Care: Protocol of a Multicentre Feasibility Randomized Controlled Trial Across Italy and Finland

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Findings:

This protocol describes an international multicenter study concerning wearable monitoring devices for patients with chronic disease in a primary care setting.

ABSTRACT

BACKGROUND: Wearable monitoring devices (WMDs) have emerged as a promising tool for supporting self-management of chronic conditions, but sustained long-term use remains a challenge. This multicentre feasibility randomized controlled trial aims to develop and evaluate a proactive monitoring intervention utilizing WMDs for individuals with chronic conditions in primary care settings across Italy and Finland.

METHODS: The intervention will be developed following the Medical Research Council framework, guided by the Self-Determination Theory. Focus groups with stakeholders will inform the design of the intervention procedures, training materials, and strategies to promote sustained WMD use by facilitating competence, autonomy, and relatedness. The feasibility trial will randomize participants to either the WMD intervention group, receiving proactive monitoring by family and community nurses, or a control group receiving standard care. Outcomes include usability, feasibility (recruitment, attrition, technical difficulties), implementation (continued use, adherence), quality of life, self-efficacy, and health service utilization. Qualitative data will explore cultural differences between the two countries.

RESULTS AND CONCLUSION: By prioritizing stakeholder engagement, theoretical grounding, and pragmatic considerations during the intervention development phase, this study aims to develop a feasible and effective proactive monitoring program to enhance chronic condition management through sustained WMD use in primary care across different European contexts, enhancing the opportunities for nurses to have advanced tools for patient monitoring and self-efficacy strategies.

KEYWORDS: *Primary care, Family and community nurses, Wearable monitoring devices, Proactive care*

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PROTOCOLLO

Monitoraggio proattivo delle condizioni croniche attraverso l'uso di Wearable Monitoring Devices (WDMs) nelle cure primarie: protocollo di uno studio multicentrico di fattibilità randomizzato e controllato in Italia e Finlandia

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Riscontri:

Questo protocollo descrive uno studio multicentrico internazionale concernente l'utilizzo di dispositive di monitoraggio indossabili per pazienti con patologie corniche in contesto di cure primarie.

ABSTRACT

BACKGROUND: I dispositivi di monitoraggio indossabili (WMD) sono uno strumento promettente per supportare l'autogestione delle condizioni croniche, ma l'uso prolungato a lungo termine rimane una sfida. Questo studio multicentrico di fattibilità, randomizzato e controllato, ha l'obiettivo di sviluppare e valutare un intervento di monitoraggio proattivo che utilizzi i WMD per persone con patologie croniche in contesti di cure primarie in Italia e Finlandia.

METODI: L'intervento sarà sviluppato seguendo il quadro del Medical Research Council, guidato dalla teoria dell'autodeterminazione. I focus-group con le parti interessate informeranno la progettazione delle procedure di intervento, dei materiali di formazione e delle strategie per promuovere l'uso sostenuto dei WMD facilitando la competenza, l'autonomia e la relazione. Lo studio di fattibilità randomizzerà i partecipanti al gruppo di intervento sull'ADM, che riceverà un monitoraggio proattivo da parte di infermieri di famiglia e di comunità, oppure a un gruppo di controllo che riceverà un'assistenza standard. Gli esiti comprendono l'usabilità, la fattibilità (reclutamento, abbandono, difficoltà tecniche), l'implementazione (uso continuato, aderenza), la qualità della vita, l'autoefficacia e l'utilizzo dei servizi sanitari. I dati qualitativi esploreranno le differenze culturali tra i due Paesi.

RISULTATI E CONCLUSIONI: Dando priorità al coinvolgimento degli stakeholder, alle basi teoriche e alle considerazioni pragmatiche durante la fase di sviluppo dell'intervento, questo studio mira a sviluppare un programma di monitoraggio proattivo fattibile ed efficace per migliorare la gestione delle condizioni croniche attraverso l'uso sostenuto dei MMG nelle cure primarie in diversi contesti europei, aumentando le opportunità per gli infermieri di avere strumenti avanzati per il monitoraggio dei pazienti e strategie di autoefficacia.

KEYWORDS: *Assistenza primaria, Infermieri di Famiglia e di Comunità, Dispositivi di monitoraggio indossabili, Assistenza proattiva*

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BACKGROUND

Chronic conditions, such as cardiovascular diseases, respiratory disorders, and cancer, remain one of the most significant challenges of healthcare systems, including in European countries. (1, 2) Primary care plays a crucial role in maintain social, economic and environmental sustainability of healthcare systems through health promotion, disease prevention and chronic condition management. Health systems are looking at innovative solutions as a mean to bridge gaps in healthcare integration and fragmented care delivery between primary and acute care services, as well as to meet service demands with limited resources, amid growing workforce shortages. (3-5) In this landscape, the new generation of innovations must enhance monitoring, self-management support, and care coordination for individuals with chronic conditions. (4)

To address these challenges, healthcare organizations are exploring new models of care delivery, such as interdisciplinary team-based approaches, integration strategies, and the introduction of advanced nursing roles like Family and Community Nurses (FCNs). (5-7) These innovative models aim to improve population health, patient experience, and reduce costs by better coordinating services for high-risk patients and those with chronic conditions. (8-10)

Wearable monitoring devices (WMDs) have emerged as a promising tool for supporting self-management and promoting healthy behaviours among individuals with chronic conditions. (11, 12) These devices can continuously monitor various health parameters, such as physical activity, sleep patterns, and physiological biomarkers, providing real-time data to both patients and healthcare providers. (13) By leveraging this data, proactive monitoring programs can be implemented in primary and acute care settings, enabling healthcare providers to closely monitor patients' health status, identify potential issues early, and provide timely interventions. (11, 14)

Previous studies have shown the potential benefits of using WMDs in chronic condition management, including improved disease control, increased physical activity levels, and enhanced self-efficacy.(15) However, the sustained use of WMDs for long periods of time remains a challenge, with reported abandonment rates exceeding 30% within a few months of adoption. (16, 17) Addressing this challenge is crucial to realizing the full potential of WMDs in chronic condition management.

The Self-Determination Theory (SDT) provides a theoretical framework for promoting sustained behaviour change and adherence to interventions. (18, 19) According to SDT, individuals are more likely to adhere to a particular behaviour when they have intrinsic motivation, which is determined by three key factors: competence, autonomy, and relatedness. (19). By integrating SDT principles into proactive monitoring programs, healthcare providers can foster intrinsic motivation among patients, potentially improving adherence to WMD use and enhancing self-management behaviours. (20, 21)

While previous studies have explored the use of WMDs in chronic condition management, few have investigated the application of SDT in promoting sustained WMD use within primary care settings across different cultural contexts. (22) Current European policy is looking at care standardization across Europe and at wide scalability of its technological innovations, considering local characteristics. (23) Considering the variations in healthcare systems, cultural norms, and patient preferences across European countries, it is essential to assess the feasibility and potential effectiveness of proactive monitoring programs using WMDs in diverse primary care settings.

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This multicenter feasibility randomized controlled trial aims to develop, implement, and evaluate an intervention focused on a proactive monitoring program utilizing WMDs for individuals with chronic conditions in primary care settings across two European countries, Italy and Finland. The program will leverage the expertise of registered nurses. By exploring the feasibility, usability, and potential effectiveness of the program, this study will contribute to understanding the application of SDT in promoting sustained WMD use for chronic condition management across different cultural contexts.

Main Aim

Phase 1: Intervention Development

To develop a proactive monitoring intervention utilizing WMDs (WMD) for individuals with chronic conditions in primary care settings across Italy and Finland.

Phase 2: Feasibility and Piloting

To assess the feasibility of implementing the proactive monitoring intervention developed in Phase 1 in primary care settings across Italy and Finland.

Secondary Aims:

To evaluate the usability of the WMD among individuals with chronic conditions, including their attitudes, perceived usefulness, ease of use and facilitating conditions related to using the device.

To assess the feasibility of the study design and of the newly developed proactive monitoring program in terms of recruitment rate, attrition rate, and incidence of reported technical difficulties and fidelity to the intervention.

To explore the potential effectiveness of the proactive monitoring program on quality of life, self-efficacy, and health service utilization among individuals with chronic conditions.

To identify any cultural or contextual differences in the implementation and outcomes of the proactive monitoring program between the two countries (Italy and Finland).

METHODS

Theory Framework

This feasibility randomized controlled trial will follow the Medical Research Council (MRC) framework for developing and evaluating complex interventions, which provides guidance on the process of defining the evidence base, identifying appropriate theory, modeling processes and outcomes, and assessing feasibility before proceeding to a full-scale evaluation(24). The study will be guided by the Self-Determination Theory (SDT), which posits that individuals are more likely to adhere to a particular behaviour when they have intrinsic motivation, determined by three key factors: competence, autonomy, and relatedness. (18, 25)

Intervention Development Phase (MRC Framework)

Prior to conducting the feasibility RCT, an intervention development phase will be carried out following the guidelines of the MRC framework. This preliminary phase aims to develop the proactive monitoring intervention procedures and components through active engagement with key stakeholders, including registered nurses from primary care settings and patients with chronic conditions in Italy and Finland. Additionally, a logic model will be created to articulate the theoretical foundations, components, and hypothesized mechanisms through which the intervention is expected to promote sustained WMD use and improved outcomes.

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Focus Groups with Stakeholders

A series of focus groups (FGs) will be conducted in both Italy and Finland to gather input from stakeholders involved in the delivery and receipt of the proactive monitoring intervention. These will include:

1. FGs with RNs from primary care settings to explore their perspectives, concerns, and recommendations regarding the intervention procedures, their roles and responsibilities, training needs, technical support requirements, and strategies to promote patient engagement.
2. FGs with chronic patients to understand needs, potential barriers and facilitators to using WMDs, communication preferences with the RNs, perceived feasible goal- setting and strategies to sustain their engagement.

The FGs will follow a semi-structured interview guide. Key points of interest, based also on previous known challenges and facilitators include logistics of intervention delivery, training needs, technical support, communication channels between nurses and patients, goal-setting processes, and strategies to promote sustained engagement.

Intervention Procedure Development

Based on the insights coming from the FGs in both countries, the research team will iteratively develop and refine the intervention procedures in collaboration with stakeholder representatives. This will involve:

- Clearly defining the roles and responsibilities of RNs in monitoring patient data from WMDs, providing feedback, and supporting patients in the proactive monitoring program.
- Establishing detailed protocols for setting goals and action plans with patients based on the WMD data and Self-Determination Theory principles.
- Determining the frequency, modality (e.g., in-person, telephone, digital platforms), and content of follow-ups and communication between registered nurses and patients.
- Identifying specific strategies to address potential barriers and facilitate the sustained use of WMDs among patients, based on stakeholder input.
- Based on RNs' level of digital literacy, developing comprehensive training materials and resources for RNs on using the WMDs, accessing and interpreting patient data, troubleshooting technical issues, and delivering the intervention components effectively.
- Based on RNs' level of digital literacy, developing educational resources and guidelines for patients on using the WMDs, understanding the data, and engaging with the monitoring program.

An important step will be providing comprehensive training for RNs on downloading the WMD app, accessing and interpreting patient data from the app, and troubleshooting technical issues that patients may encounter. This is to directly address the lack of familiarity with the WMD technology highlighted as a barrier in previous studies.

Logic Model Development

Concurrently, a comprehensive logic model will be developed to articulate the theoretical underpinnings, components, and hypothesized mechanisms through which the proactive monitoring intervention is expected to promote sustained WMD use and improved outcomes among patients with chronic conditions. The logic model will be informed by the Self-Determination Theory, stakeholder input, and

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existing evidence from the literature. The logic model will outline the intervention inputs, key activities, outputs, and connection to short-term, intermediate (e.g., adoption of healthy behaviors, better disease management), and long-term outcomes (e.g., improved quality of life, reduced healthcare utilization).

Study Design

This is a multicentre feasibility randomized controlled trial (RCT).

Data Collection

Different streams of data will be collected. WMD data will be continuously collected for three months through the WMD. Self-efficacy and quality of life data will be collected at baseline, 1 month, 3 months (end of intervention), and 6 months (follow-up) using validated questionnaires. Healthcare utilization will be collected for up to 1 year from electronical healthcare records.

Settings

Italy and Finland have been selected as the two European countries for this multicenter trial due to their different characteristics in terms of social and health behaviours, which will provide valuable insights into the feasibility and potential effectiveness of the proactive monitoring intervention across different contexts in Europe. The Italian healthcare system is a regionally- based national health service, with each region having a significant degree of autonomy in organizing and delivering healthcare services. This decentralized approach allows for the implementation and evaluation of innovative care models tailored to local needs and resources(26). Additionally, Italy faces challenges such as workforce shortages, particularly in primary care, making the exploration of new care delivery models involving advanced nursing roles a priority(27). In contrast, Finland has a highly decentralized healthcare system, with municipalities responsible for organizing and providing primary and secondary care services(28). This system is characterized by a strong emphasis on primary care and preventive services, aligning well with the goals of the proactive monitoring intervention. Furthermore, Finland has been at the forefront of adopting digital health technologies and exploring their integration into routine care(29).

Population

Users with 1 or more chronic conditions followed in primary care settings two different European countries, Italy and Finland.

Intervention

Intervention will follow the MRC framework. Patients will be proactively monitored by a registered nurse (RN). Patients who accept to be part of the study will be randomized to either WMD group or standard of care. Patients in the WMD group will be proactively followed by the RN, which will receive the health statistics. The WMD will passively monitor patients and provide to both patients and nurses with weekly reports of health statistics. The intervention will explicitly target these three factors to sustain participants' intrinsic motivation for continued use of wearable monitoring devices (WMDs). Competence will be facilitated through in-person demonstrations and training on using the WMD and interpreting health statistics, provided by RNs. Autonomy will be promoted by encouraging participants to set personalized goals and action plans based on the health data, with guidance from FCNs. Relatedness will be fostered through regular follow-ups by RNs, addressing concerns or barriers to using the WMD and providing ongoing support.

Setting

The study will be conducted in the primary care setting, in two different countries.

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Participants

Inclusion criteria will be adolescents (aged 14 and older) and adults (aged 18 years and above), diagnosed with one or more of chronic conditions and willing to use a WMD and an app to monitor their health. Specific exclusion criteria will be cognitive impairment, lack of a smartphone supporting WMD technology and Inability to provide informed consent.

Intervention

Participants in the intervention group will be proactively monitored by a RN in primary care using the WMD, a commercially available WMD. The WMD will passively monitor participants' health statistics, including activity, sleep, heart rate, and physiological biomarkers. Participants and nurses will receive weekly reports summarizing these health statistics.

The intervention components will explicitly focus on facilitating the three motivational factors outlined by SDT. Competence: RNs will provide in-person demonstrations and training on using the WMD and interpreting the health statistics. Autonomy: Participants will be encouraged to set personalized goals and action plans based on the health statistics, with guidance from the RN. Relatedness: RNs will conduct regular follow-ups with participants, addressing any concerns or barriers to using the WMD and providing ongoing support.

Control Group

Participants in the control group will receive standard care, without proactive monitoring or the use of the WMD.

Randomization

Participants will be randomly assigned to either the intervention or control group using a computer-generated randomization sequence.

Outcomes

The study will assess the following outcomes:

1. Usability of the WMD: Attitudes toward using the WMD, Perceived usefulness, Perceived ease of use, Self-efficacy in using the device, facilitating conditions for using the device
2. Feasibility: Recruitment rate, Attrition rate, Incidence of reported technical difficulties
3. Implementation: Continued use intention, Adherence rate (number of days and hours the WMD is worn)
4. Quality of life, Self-efficacy, Health service utilization

Usability will be evaluated through qualitative data and observations.

Feasibility will be evaluated through a recruitment log to calculate the recruitment rate, attrition tracking for the attrition rate, and an incident reporting system for documenting technical difficulties.

Implementation outcomes include continued use intention and adherence rate measured by the number of days and hours the WMD is worn, continuously collected by the device. Health outcomes comprise quality of life (WHOQOL-BREF)(30, 31), self-efficacy (Global Physical Activity Questionnaire(32); Stress Management Self Efficacy Inventory(SMSEI)(33), and health service utilization data extracted from electronic health records. The application of Self-Determination Theory will be examined through qualitative data and observations, exploring competence, autonomy, and relatedness. Similarly, qualitative methods will identify cultural/contextual differences in implementation and outcomes between Italy and Finland.

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Sample Size

Considering an average WHOQOL-Bref score of 75 (mean population) and a standard deviation of 10 in a population of adult patients with chronic diseases(34), and estimating an increase in the average score of 5 points (mean study group = 80) due to our intervention, the power analysis we conducted suggested the need to enrol at least 31 participants, with an alpha level of 0.05, a beta of 0.2, and a power of 0.8. Considering a potential drop-out rate of 10%, we will aim to enrol a total of 35 patients in our study group.

Data Analysis:

Descriptive statistics will be used to summarize the baseline characteristics and feasibility outcomes. Generalized estimating equations will be employed to assess differences or changes between the intervention and control groups, within-group effects, and interaction effects for the effectiveness outcomes. Intention-to-treat analysis will be implemented as the primary method for addressing missing data.

The qualitative data collected will be analyzed using content analysis. All discussions and interviews will be audio-recorded with participants' consent. The audio recordings will then be transcribed verbatim and imported into a qualitative data analysis software, NVivo, to facilitate the coding and analysis process.

The content analysis will follow an iterative and systematic approach. Initially, the research team will perform open coding, where they will carefully read through the transcripts and assign codes to relevant segments of text, allowing themes and concepts to emerge from the data. This inductive coding process will be followed by axial coding, where the researchers will identify relationships and connections between the codes and organize them into broader categories and subcategories.

Throughout the coding process, the research team will engage in constant comparative analysis, continuously comparing the codes, categories, and emerging themes across different participants, focus groups, and study sites. This comparative approach will enable the researchers to identify patterns, similarities, and differences in the qualitative data. The research team will maintain an audit trail, documenting their analytical decisions, memos, and interpretations, to enhance the transparency and trustworthiness of the qualitative analysis. Additionally, member checking may be employed, where the researchers will share their interpretations and findings with selected participants to ensure the accuracy and resonance of the analysis.

Ethical Considerations

The study will obtain approval from the relevant institutional review board(s) before commencing. The study will be conducted in accordance with the Declaration of Helsinki indications. Informed consent will be obtained from all participants, and data confidentiality will be maintained and in line with the European General Data Protection Regulation (GDPR). Data will be pseudo anonymized to ensure the secure use of de-identified data.

DISCUSSION

A recent scoping review has highlighted that the majority of DHIs developed in the context of primary care have to date been rolled out as pilot studies, without further implementation and effectiveness considerations. (5) To enhance as much as possible the implementation and scalability potential of this intervention, the intervention development phase outlined in this study protocol places the focus on practicability and feasibility considerations, drawing from the experiences and lessons learned from

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previous interventions involving WMDs and lifestyle change support in healthcare settings. (35-37)

One of the key challenges highlighted in the literature is the limited time and resources available to healthcare providers during routine care appointments. (38, 39) Complex interventions entailing counselling, education, and digital literacy require a diverse set of skills in HCPs(40). From an organizational point of view, this underscores the importance of carefully designing the proactive monitoring intervention to be time-efficient and seamlessly integrated into existing primary care workflows(36). Moreover, intervention development should be a result of the coordinated efforts of all stakeholders and end-users, to ensure the best design, use and maintenance of digital solutions. (41, 42) As Neves et al. reported, there is a need of improving infrastructure, support, and training of professionals, it is necessary to develop best practice standards and to work towards more equitable digital solutions, that leave no one behind. (40)

For this reason, the comprehensive training and educational resources developed for users will play a crucial role in facilitating the successful implementation of the intervention. A lack of familiarity with WMD technology and data interpretation can hinder patient engagement and the effective utilization of such interventions. (43, 44) By providing in-depth training on the WMD app, data access, interpretation, and troubleshooting, the intervention development phase aims to equip users with the necessary skills and confidence to navigate the technical aspects of the intervention seamlessly, without overwhelming them. (45) Additionally, the development of patient educational resources contributes to create a supportive and non-judgmental environment for participants. By ensuring that patients receive clear guidance on using the WMDs, understanding the data, and engaging with the proactive monitoring program, the intervention can foster a sense of empowerment and active participation, rather than imposing an additional burden. (44, 46)

By prioritizing stakeholder engagement, practical considerations, and a thorough understanding of the intervention's theoretical foundations and mechanisms, the research team aims to develop an intervention that is not only scientifically rigorous but also pragmatic and feasible for implementation in primary care settings across different cultural contexts.

Conclusions

This multicenter feasibility trial across Italy and Finland will provide valuable insights into the implementation of proactive monitoring programs utilizing wearable devices for chronic condition management in primary care settings across different European contexts. By integrating principles from Self-Determination Theory and actively involving stakeholders throughout the intervention development process, the study aims to enhance sustained engagement and adherence to wearable technology among patients. The findings will inform the feasibility, usability, and potential effectiveness of such interventions, as well as identify cultural and contextual factors influencing their implementation. Ultimately, this research has the potential to contribute to the development of innovative care models that leverage digital health technologies to improve disease management, self-efficacy, and quality of life for individuals with chronic conditions while reducing healthcare utilization. The lessons learned from this study can guide future efforts to scale up proactive monitoring programs and integrate them into routine primary care practice across Europe.

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