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Preliminary effectiveness of social prescription and virtual patient information in increasing tertiary prevention among cancer patients (ESPRIT): protocol for a single-centre, randomised controlled pilot trial

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ABSTRACT

Introduction Tertiary prevention through physical activity and psychosocial support can positively impact patient outcomes, such as physical function and quality of life (QoL). However, more research is required on the effectiveness of strategies designed to increase the uptake of tertiary prevention programmes among cancer patients. Here, we present the protocol for a single-centre, randomised controlled pilot trial testing the preliminary effectiveness of social prescription and virtual patient information in increasing tertiary prevention among cancer patients and support persons (SPs) (ESPRIT "**E**ffectiveness of a **s**ocial **pr**escription and virtual patient **i**nformation in increasing **t**ertiary prevention" pilot trial).

Methods and analysis Cancer patients attending medical oncology units at a university hospital in southern Germany and their SPs will be randomly allocated as a dyad to group A (social prescription (n=36)), group B (virtual patient information (n=36)) or group C (usual care (n=36)). The hospital is part of a Comprehensive Cancer Centre mainly treating patients living in rural areas. Primary outcomes are the uptake of physical activity, participation in social activities and psychosocial support. Secondary outcomes are overall QoL, knowledge of the health benefits of physical activity and psychosocial support and self-efficacy of patients. The outcomes will be assessed at baseline and after 3, 6 and 12 months of follow-up. Physical activity will be assessed using accelerometers and measured by average steps per day within the last 2 weeks after recruitment and at follow-up visits (3, 6 and 12 months). Cost-effectiveness and the time spent in the consultation, as well as potential implementation barriers and facilitators, will also be explored as part of a mixed-methods hybrid design. All data will be summarised descriptively. Regarding the analysis of primary endpoints, the average number of steps per day, as well as the summary score of the social activity log and self-report on the use of psychosocial support, will be compared between the groups (A, B and C) using analysis of variance, followed by Dunnett's test for pairwise comparisons of the intervention groups against the control group. Mean differences and 95% CIs will be presented as effect estimates. The analysis of secondary endpoints will include appropriate statistical methods such as the χ^2 test of independence or linear regression models, which will be used to analyse secondary endpoints and to investigate factors influencing preliminary effectiveness.

Ethics and dissemination This trial has been approved by the ethics committee of the University of Regensburg (reference: 23-3317-101). Signed written informed consent is required from all study participants. The results of the study will be used to inform the power calculation for future confirmatory trials and will be submitted for publication.

Trial registration number DRKS00033771.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This pilot trial employs innovative methodology by using an effectiveness-implementation hybrid design.
⇒ Levels of physical activity will be measured using accelerometers rather than self-report.
⇒ A mixed-methods approach allows for comprehensively assessing the care experiences and preferences of cancer patients and support persons.
⇒ This project is conducted in close collaboration with a comprehensive cancer centre, mainly treating patients from rural areas, to assess potential barriers to care access.
⇒ Given that this is a single-centre pilot trial, further exploration of the generalisability of findings will be required.

INTRODUCTION

Tertiary prevention involves minimising the effects of cancer and its treatment, improving patients' quality of life (QoL)

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and preventing disease progression. Through physical activity and psychosocial support during and after cancer treatment, various patient outcomes can be improved, for example, increased fitness and physical functioning or reduced fatigue.[1–3] Also, a number of studies found that the use of tertiary prevention programmes can decrease anxiety and depression among cancer patients.[4] This may result in long-term healthcare cost savings.[5–7] There is evidence that cancer patients are interested in becoming more physically active and receiving further supportive care.[8–10] Numerous programmes have been designed to meet patients' need for improved tertiary prevention, including strength and resistance training or yoga.[11 12] Such programmes have been shown to be acceptable to patients and effective in improving patient outcomes, such as increased overall QoL or reduced fatigue.[9 12] However, adoption rates of tertiary prevention programmes remain low.[13] For example, a German multicentre study involving 4020 cancer patients diagnosed with a mental disorder found that less than half reported having taken up psychological support offers.[14] Various barriers to the uptake of tertiary prevention programmes have been identified, including patients' and clinicians' lack of knowledge about the potential benefits of physical activity and psychosocial support as well as limited access to appropriate offers.[15 16]

A number of strategies have been developed to increase the uptake of tertiary prevention programmes, including the use of personal counselling and wearable device-based interventions.[5 6 17] Despite this, little is known about which strategies are most effective in improving patient outcomes and should thus be implemented into clinical practice.[13] Reviews suggest that multidisciplinary strategies tailored to the individual needs of patients may be most effective, but current evidence remains inconclusive.[18–20] There is also a lack of evidence on the cost-effectiveness of interventions designed to increase tertiary prevention among cancer patients.[21]

It has been suggested that the involvement of patients and their support persons (SPs) as dyads may enhance the uptake of physical activity and psychosocial support, as SPs can positively impact patients' preventive health behaviour.[22] However, only a few studies have explored how to best use the bond between patients and SPs to increase the uptake of tertiary prevention programmes.[23 24]

One novel and promising strategy to facilitate the use of tertiary prevention among cancer patients is social prescribing. Social prescribing involves interactions between physicians and patients resulting in written referrals to non-clinical support programmes to meet patients' physical and mental health needs.[22] This referral process involves various healthcare services and is tailored to the individual needs of each patient.[25] Social prescribing has been shown to improve patients' self-perceived health status and to reduce social isolation.[26 27] It may also enhance multidisciplinary care and, at the same time, reduce the workload for healthcare professionals.[28 29]

The current pilot trial uses an effectiveness-implementation hybrid design[30] to explore the preliminary effectiveness and implementability of social prescription and virtual patient information concerning physical and social activity, as well as psychosocial support services, in increasing tertiary prevention among cancer patients.

METHODS AND ANALYSIS

Study design and setting

This is a single-centre pilot randomised controlled trial (RCT) in the context of a Comprehensive Cancer Centre (CCC) at a university hospital in southern Germany, mainly treating patients living in rural areas. The study will investigate the preliminary effectiveness of social prescription (group A) and virtual patient information (group B) compared with usual care (group C) in increasing the uptake of (1) physical activity among cancer patients measured by average steps per day over 2 weeks after recruitment and follow-up visits (3, 6 and 12 months) and (2) participation in social activities and psychosocial support among cancer patients and SPs (see figure 1). The nature of this study is explorative, rather than confirming a priori hypothesis.

Participants

The study includes German-speaking adult patients (aged ≥18 years) attending medical oncology units at the participating hospital, diagnosed with early-stage or advanced cancer (ie, cancer stages I–IV) no more than 12 months ago, who have an expected survival of at least 2 years and will have provided written informed consent (see online supplemental material for an example of the consent form). SPs are also included if they are German-speaking, aged ≥18 years, nominated by the patient as someone helping them cope with their cancer through support, encouragement and communication, and have provided written informed consent. Key exclusion criteria involve an inability to complete surveys or interviews independently (eg, speech and vigilance). Corresponding clinicians (eg, physicians) working at the participating clinic will be invited to take part in interviews exploring barriers and facilitators to the implementation of the interventions.

Recruitment

Patients are identified systematically from clinic lists prior to their appointment through a member of the study team. The treating physician informs patients about the ESPRIT pilot trial during an outpatient clinic visit and asks for consent to be contacted by a member of the research team, who will provide them with further verbal and written study information and obtain informed consent. If SPs are not present in the clinic, patients are asked to hand a study information package to their SPs. Patients only participate if SPs participate, and vice versa, to allow for the examination of changes in the outcomes

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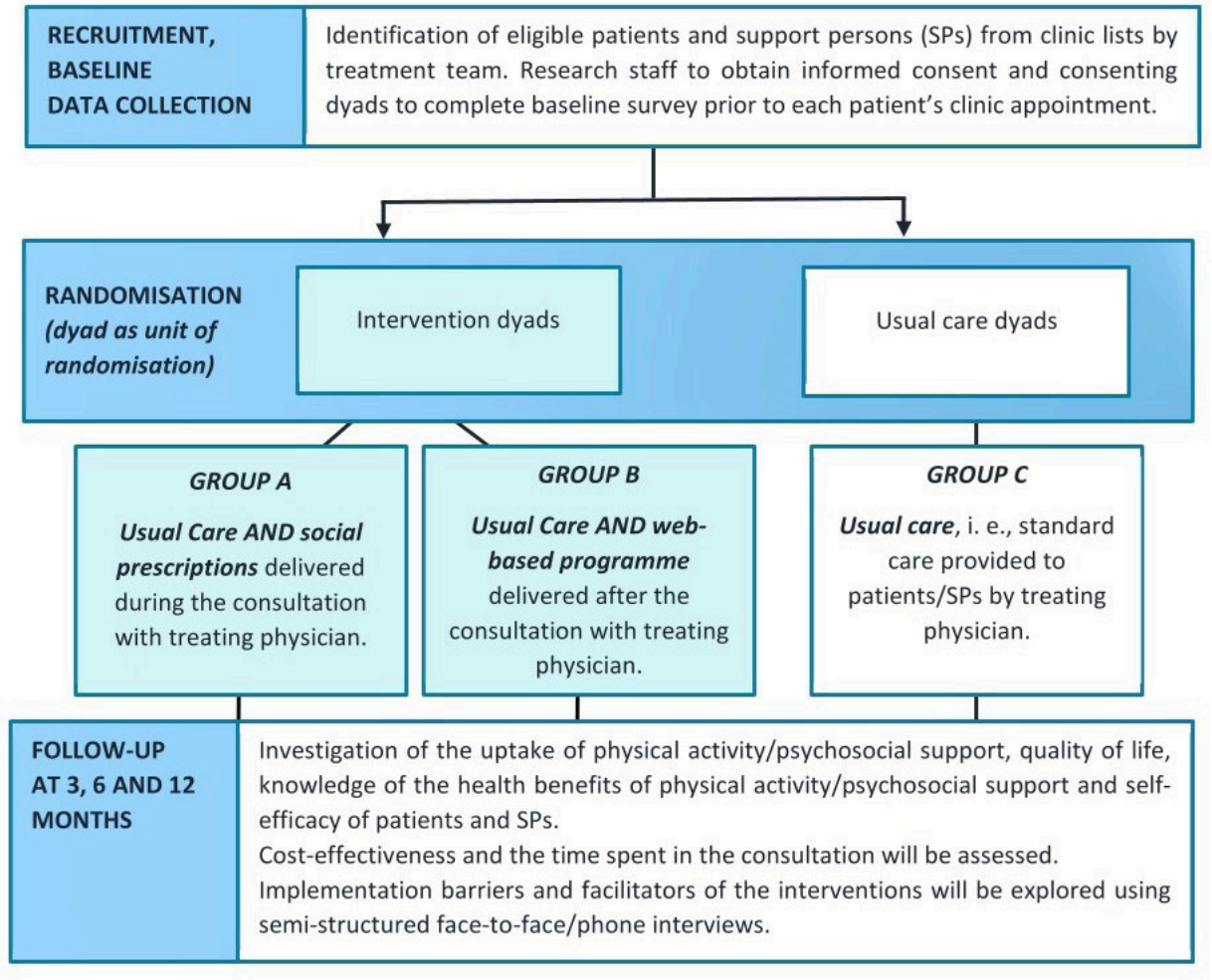

Figure 1 Study workflow.

of patient-SP dyads. A subsample of patients, SPs and clinicians will be recruited for a qualitative substudy assessing implementation barriers and facilitators. Recruitment started in July 2024 and is currently ongoing.

Randomisation

Patients and SPs are randomised as a dyad and allocated to receive either intervention A or intervention B or usual care only (group C). Block randomisation is used to achieve an equal distribution of treatment options (A, B and C).

Development and description of the interventions

This project involves a comparison of two innovative interventions to help determine the most effective strategy and investigate factors influencing preliminary effectiveness and implementation. The aim of the interventions is to increase the uptake of physical activity and psychosocial support among cancer patients and SPs. The interventions will be delivered during (group A) or after (group B) the consultation with the treating physician (see figure 1). The interventions are based on a literature review and currently available guidelines and were developed by a multidisciplinary team involving experts in the areas of oncology, physiotherapy, behavioural science and communication science, as well as representatives of patients and SPs.

Group A—social prescription: intervention A includes individualised care plans that are tailored to each patient's medical condition to suit their particular needs and allow for the application of the social prescription to a wide range of cancer patients. The social prescription conveys information on the benefits of an active lifestyle, participating in social groups and available programmes to become physically active and receive psychosocial support for patients and SPs. The social prescription is initially delivered by the treating physician during the consultation with the patient and their SP. The social prescription is programmed with the help of REDCap, which is a versatile open-source software. The one-page prescription is generated using patient-reported outcome data on participants' health and well-being. These data are gathered with the help of the baseline questionnaire. Algorithms were designed to help provide individually tailored recommendations based on patients' responses. For instance, the distress thermometer is used, and in line with internationally agreed-upon guidance, patients are referred to a psycho-oncologist if they score five or above.[31]

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Group B—virtual patient information: intervention B involves a web-based programme presenting video information about the health benefits of physical activity and psychosocial support as well as available programmes to become physically active and seek further psychosocial support. This virtual patient information is developed by the research team. The treating physician provides participants with access to the virtual patient information during the consultation, which participants can then access after the consultation.

Group C—control group usual care: the usual care group receives standard care from their cancer care providers. Usual care does not include individualised prescriptions.

Outcomes

Primary outcomes are the uptake of physical activity, participation in social activities and psychosocial support. Secondary outcomes are overall QoL, knowledge of the health benefits of physical activity and psychosocial support and self-efficacy of patients. Potential implementation barriers and facilitators and cost-effectiveness will also be explored. The outcomes will be assessed at baseline and 3, 6 and 12 months follow-up.

Primary outcomes

Uptake of physical activity is measured by average steps over 2 weeks after recruitment and follow-up visits (3, 6 and 12 months), using wearable accelerometers (ActiGraph wGT3X-BT).[21 32] For the current study, wearable accelerometers are deemed the most appropriate means of measuring physical activity as they may provide a more objective method than participant self-report, which may lack accuracy.[33] Accelerometers are also considered superior to pedometers since they provide additional data about the frequency, intensity, type and duration of physical activity, rather than reporting on step count only.[33] This additional information will help inform the interpretation of the study results. The uptake of participation in social activities and psychosocial support will be assessed using a summary score involving the social activity log (SAL)[34 34] and participant self-report on the use of psychosocial support services. The SAL was designed to capture the frequency and diversity of social activities outside of daily responsibilities and has been previously used to provide an understanding of cancer patients' social behaviour.[34] It was refined and adapted to the German context using forward-backward translation.

Secondary outcomes

QoL will be assessed using the EORTC QLQ-C15-PAL, which is a widely used, coherent and easily administered quality-of-life measure using patient self-report.[35 36] It consists of 15 questions assessing key aspects of QoL, such as physical, cognitive, social and emotional functioning. The QLQ-C15 PAL is a shortened version of the QLQ-C30 [37] and is supposed to reduce the research-related burden on the patients.

Knowledge of the benefits of physical activity and psychosocial support is examined based on additional information provided as part of the interventions and will be assessed with a self-designed questionnaire that consists of 14 items. The proportion of accurate responses will be transformed to a percentage scale ranging from 0% (no correct responses) to 100% (perfectly accurate responses).[38]

Self-efficacy, that is, the individual's capacity to produce the desired effects,[39] is assessed using the Cancer Behaviour Inventory (CBI-B-D)—Brief Version.[40] The CBI-B-D is a valid, brief measure of self-efficacy strategies for coping with cancer, which can be easily integrated into clinical oncology research and practice.[40]

To investigate explanatory variables, date of birth, gender, residential postal code, occupation and highest level of education will be assessed. Furthermore, cancer type, time since diagnosis, grade and stage of cancer at diagnosis are identified using medical records to reduce the research-related burden on patients and to ensure the validity of the data.

Participants' level of cancer literacy is assessed using the German version of Cancer Health Literacy Test-6, which is a validated brief measure to assess individuals' ability to locate, understand, evaluate and apply health information to make informed decisions about their health.[41 42]

To examine the potential implementation barriers and facilitators, qualitative semistructured interviews will be conducted with a purposeful subsample of patients, SPs and clinicians. This approach has been widely used to assess the intervention process and has been shown to be able to shed light on novel phenomena relevant to interventions.[43] Relatively little is known about how to implement strategies shown to be most effective in increasing tertiary prevention among cancer patients in order to help translate findings from research into clinical practice.[14] Longitudinal qualitative data will be used to help fill this gap by exploring implementation barriers and facilitators over time and assessing how the most effective intervention could be best used in routine cancer care. Cancer patients and SPs will be asked semistructured open-ended questions about their perceptions of barriers and facilitators, including the acceptability of the intervention, ease of use and practicability, agreement with specific components of the intervention, motivation to use the intervention and self-efficacy (ie, belief that one can interpret and use the intervention). In addition, qualitative interviews with clinicians will be conducted to explore their views on the perceived complexity of the intervention and environmental factors that could impede the use of the interventions, such as time constraints and costs associated with supportive care.

The time spent in the consultation will be assessed to help ensure that providing the intervention will not require physicians to spend more time in the consultation and will cause minimal, if any, disruption to the clinical workflow.

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Engagement with the virtual patient information will be collected by recording user activity across the intervention period.

Data collection, management, analysis and monitoring

Regarding non-consenters, the year of birth and gender are collected. The outcome data from those who do not use the intervention is collected. The data management and data protection concepts were part of the ethics application. The description of any interim analyses and guidelines for study termination will be decided by the research team.

Sample size

The primary aim of this pilot trial is an assessment of the intervention regarding its preliminary effectiveness measured by the two primary endpoints, physical activity and social participation/psychosocial support. Further, effect estimates of this study should be used as preliminary information for justification of the sample size for a large confirmatory trial.[44–46] To estimate the therapeutic effects with sufficient accuracy, a total of n=36 patients-SP dyads per group are planned, as proposed by Hertzog.[46] Hertzog explicitly recommends sample sizes of 30–40 participants per group if direct estimation of a between-group effect size is desired in order to yield CIs that can help define the range of plausible values for a subsequent power analysis.[46] Assuming a drop-out rate of ~20%, we plan to include 36 dyads per arm, and 30 dyads per arm will be analysed.

For the qualitative analysis, data collection will be discontinued when data saturation in each group is perceived to be reached and further data gathering is not likely to reveal additional findings to answer the research question.[47 48] In line with previous studies, we anticipate that conducting 30 interviews with patient-SP dyads in each study and control arm and at different points in time (ie, at baseline, 3, 6 and 12 months follow-up) provides a feasible approach to reach data saturation.[49–51]

Statistical analysis

All data will be summarised descriptively by presenting numbers of observations, means, quartiles/IQR, SD, medians, minimums and maximums for continuous data, and absolute and relative frequencies for categorical data, both overall and for each treatment group. For the analysis of primary endpoints, the average number of steps per day, summary score of SAL and self-report on the use of psychosocial support will be compared between the groups (interventions A, B and control) using analysis of variance, followed by Dunnett's test for pairwise comparisons of the intervention groups A and B against the control group C. Mean differences and 95% CIs will be presented as effect estimates. Regarding the analysis of secondary endpoints, we use appropriate statistical methods depending on the scale level of the variables and the exact research question that will be applied, for example, to study factors influencing preliminary effectiveness such as self-reported independent measures or disease-related characteristics. For both primary and secondary analyses, a p value of <0.05 will be considered statistically significant without adjustment for multiple testing, given the explorative and hypothesis-generating nature of the study. A statistician/biometrician will supervise the data management and data analysis and work out a detailed statistical analysis plan prior to analysis.

Qualitative data analysis

Interviews will be transcribed verbatim. Transcripts will be checked for accuracy by one researcher and analysed using framework analysis.[52] This approach is part of a broad family of qualitative data analysis methods often referred to as 'thematic analysis' or 'qualitative content analysis'.[8] As suggested by these approaches, both descriptive and explanatory conclusions will be drawn from the data. This method of qualitative data analysis will provide a systematic model for mapping and interpreting the data and is thus considered appropriate to develop a profound in-depth understanding of participants' experiences and views.[53]

Patient and public involvement

Representatives of patients, SPs and clinicians were involved in the conceptualisation of this study, as well as in the development of the study-specific patient information and interventions. They will also provide ongoing advice and support during data collection, data analysis and report writing.

Study timeline

The study is planned to be completed in early 2026. Baseline recruitment is planned to finish in April 2025.

ETHICS AND DISSEMINATION

This trial has been approved by the ethics committee of the University of Regensburg (reference: 23-3317-101). Signed written informed consent is required from all study participants. The requirements for the consent documents include, among other things, that they: (a) must be written in layman's terms, (b) must be comprehensive, (c) the risk must be objectively assessable and must be referred to in particular, (d) side effects must be clearly stated and (e) both information about the study and consent must be separate documents. The results of the study will be used to inform the power calculation for future confirmatory trials. Furthermore, the results will be submitted for publication in peer-reviewed journals as well as disseminated in lay language in newspapers/public science magazines.

The study was registered at Deutsches Register Klinischer Studien (DRKS, DRKS00033771) on 3 March 2024.

DISCUSSION

This article presents the rationale and design of the ESPRIT pilot trial and the process of tailoring

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information about physical activity and psychosocial support through social prescription to cancer patients and their SPs. The ESPRIT trial is a single-centre, randomised controlled pilot trial designed to test the preliminary effectiveness of social prescribing and virtual patient information in increasing tertiary prevention among cancer patients and SPs. Further analyses will be carried out to examine preliminary cost-effectiveness and implementation barriers and facilitators. A strength of this study is its randomised controlled design and the interdisciplinary development of interventions to ensure appropriate tailoring of care recommendations. This pilot RCT uses an innovative methodology by employing a hybrid effectiveness-implementation design. To maximise the accuracy of measuring patients' physical activity, we use accelerometers rather than relying on patient self-report. Another strength is that a mixed-method approach will allow a comprehensive assessment of the care experiences and preferences of cancer patients and SPs as well as clinicians' views on acceptability and usability of the interventions. With this information, interventions could be improved before further recommendations for clinical practice can be considered.

When it comes to the limitations of the study, it should be mentioned that this project is conducted in close collaboration with a CCC mainly treating patients from rural areas to assess potential barriers to care access. The results cannot be directly transferred to other centres as clinical contexts may differ. However, the results can serve as a blueprint and provide initial insights for centres considering introducing patient-centred care concepts such as social prescribing. Given that this is a single-centre pilot trial, further exploration of the generalisability of findings will be required.

This study will contribute to the evidence base on how to increase physical activity and psychosocial support among cancer patients during and following treatment. If preliminary effectiveness is demonstrated, the implementation of the developed intervention in clinical practice may be supported to help create meaningful benefits for patients and their SPs.

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