BMJ Nutrition, Prevention & Health

Promotion of Physical Activity by Health Professionals (PROMOTE-PA): protocol for effectiveness outcomes in a hybrid type I effectiveness-implementation cluster randomised controlled trial

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To cite: Baldwin JN, Purcell K, Hassett L, *et al*. Promotion of Physical Activity by Health Professionals (PROMOTE-PA): protocol for effectiveness outcomes in a hybrid type I effectiveness-implementation cluster randomised controlled trial. *BMJ Nutrition, Prevention & Health* 2024;**0**:e000901. doi:10.1136/bmjnph-2024-000901

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Received 4 March 2024
Accepted 23 July 2024

ABSTRACT

Promotion of physical activity by health professionals can increase physical activity participation among patients, however, implementing physical activity promotion within hospital systems is lacking. The Promotion of Physical Activity by Health Professionals (PROMOTE-PA) study is a hybrid type I effectiveness-implementation cluster randomised controlled trial evaluating the effectiveness of support for physical activity promotion by health professionals on physical activity participation of patients. Health professionals delivering outpatient healthcare services within four local health districts and one specialty health network in New South Wales, Australia will be included. The target patient population is children (5–17 years) and adults (18+ years) who are willing to receive additional support to be more physically active. The evidence-based intervention is brief physical activity promotion informed by the '5As' physical activity counselling model and behavioural theory, embedded into routine clinical practice. Our multi-faceted strategy to support implementation of physical activity promotion was developed based on preliminary research and consultation with key stakeholders. The implementation strategy includes education and training as well as a selection of the following (tailored to each clinical team): community referral strategies, experts and clinical mentors, and clinical champions. 30 outpatient clinical teams will be randomised to receive the implementation strategy immediately or after a 3-month delay (waitlist control). Each team will seek to recruit 10–30 patients (n=approx. 720) to report moderate-vigorous physical activity (minutes per week, primary outcome), frequency of balance and strength exercise, mobility, and quality of life at baseline, 3-month and 6-month post patient recruitment. This study aims to address the increasing burden of physical inactivity in a high-risk population using the existing health workforce.

Trial registration number Australian and New Zealand Clinical Trials Registry (ACTRN12623000920695).

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Promotion of physical activity by health professionals could have a role in addressing global inactivity but evidence to guide real-world implementation is limited.

WHAT THIS STUDY ADDS

⇒ This study will evaluate the effectiveness of support for physical activity promotion by health professionals on physical activity participation of their patients.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Embedding physical activity promotion into routine clinical practice is a potentially efficient intervention to reduce chronic disease and enhance health using the existing health workforce.

INTRODUCTION

Low physical activity (PA) is a major public health issue leading to 5.3 million avoidable deaths each year.[1] Almost one in two Australians (43%) do not meet current PA guidelines

and there is no sign of improvement over time.[2] People with disability and older adults face additional barriers to PA participation.[3] There is an urgent need to develop and evaluate interventions that can be implemented at scale.[4]

PA promotion aims to change behaviour to prevent chronic conditions. Interventions that incorporate behaviour change techniques (identifying barriers, self-monitoring, goal setting and feedback) increase PA in the general population[5 6] and people with disabilities.[7] Brief interventions such as the 5As approach (Assess, Advise, Agree, Assist and Arrange)[8] can improve PA when delivered by health professionals, but evidence within hospital settings is limited.[9]

The WHO recommends that health professionals promote PA within routine care.[10] Health professionals have a strong interest in supporting their patients to be more active.[11 12] However, health professional surveys,[11 12] patient surveys[13 14] and medical record audits[13] indicate that PA promotion is not routinely delivered. Common barriers include a lack of resources, time, knowledge, skills, incentives, and limited knowledge and trust of existing community PA opportunities.[15]

The Promotion of Physical Activity by Health Professionals (PROMOTE-PA) study aims to address these evidence-practice gaps. We will deliver a multi-faceted implementation strategy supporting teams of outpatient health professionals to implement PA promotion into routine care. The purpose of this study is to test the effectiveness of the PA promotion intervention delivered by health professionals with support from researchers. We will also gather observational data on implementation outcomes and determinants. Effectiveness questions include:

1. Does PA promotion by health professionals with support from researchers, increase participation in self-reported moderate-vigorous PA (primary outcome), balance or strength exercise compared with usual care among people who receive outpatient health services?
2. Does PA promotion by health professionals with support from researchers, improve self-reported mobility and quality of life compared with usual care among people who receive outpatient health services?

Our hypothesis is that patients receiving care from health professionals who have received support will be more physically active (primary hypothesis) and have greater self-reported mobility and quality of life, than patients receiving care from health professionals who have not yet received support.

METHODS

Design

We will undertake a cluster randomised controlled superiority trial with two parallel groups, 30 clusters and approximately 720 participants (figure 1). The study will use an effectiveness-implementation hybrid type I design, with a primary focus on effectiveness. The study design is guided by the Consolidated Standards of Reporting Trials: extension to cluster randomised controlled trials,[16] and reported according to the Standard Protocol Items: Recommendations for Interventional Trials[17] and the Template for Intervention Description and Replication (TIDieR) framework.[18]

This protocol describes the effectiveness components of the PROMOTE-PA study. The protocol for exploration of processes, implementation outcomes and determinants, and the economic evaluation will be described in a separate paper.

Consumer and health professional input

This study was codesigned with our clinical/health service manager investigators (BR, DT, MJ, SG, KW) and community PA representatives (PH, JW). The implementation strategies were developed and refined with local health professional input, including managers and senior and junior health professionals, via semi-structured interviews and focus groups during part I of this study (manuscripts in preparation) as well as previous surveys,[19 20] interviews[15] and consultations[21] with health professionals.

A PROMOTE-PA consumer advisory group has been established for this study and comprises four consumer volunteers who have provided feedback on development of study information and consent forms, participant surveys and educational resources for patients. This feedback has been used to further develop trial information and consent forms. The group will meet 3–4 times per year for the duration of the trial.

Study sites and participant groups

This study will recruit through outpatient healthcare services across four Local Health Districts (Sydney, Western Sydney, South Western Sydney and South Eastern Sydney) and Sydney Children's Hospital Network within New South Wales, Australia. The local health districts include 15 public hospitals and the Sydney Children's Hospital Network includes 2 public hospitals. Private practices offering similar outpatient services to target patient groups may also be recruited.

Health professional inclusion criteria

Healthcare teams that provide a service for outpatients to the target patient groups will form each of the 30 clusters. Teams that have at least one interested health professional will be recruited, with the size of clinical teams likely to differ. Examples of clinical teams include physiotherapy outpatients, rheumatology outpatients and outpatient rehabilitation.

Health professional participants will be eligible if they:

- Are providing outpatient services within a participating clinical team.
- Have the scope to include PA promotion in their practice, including physiotherapists, occupational therapists, geriatricians, rehabilitation physicians, rheumatologists, endocrinologists, surgeons, oncologists, haematologists, sports physicians, exercise physiologists or nurses.

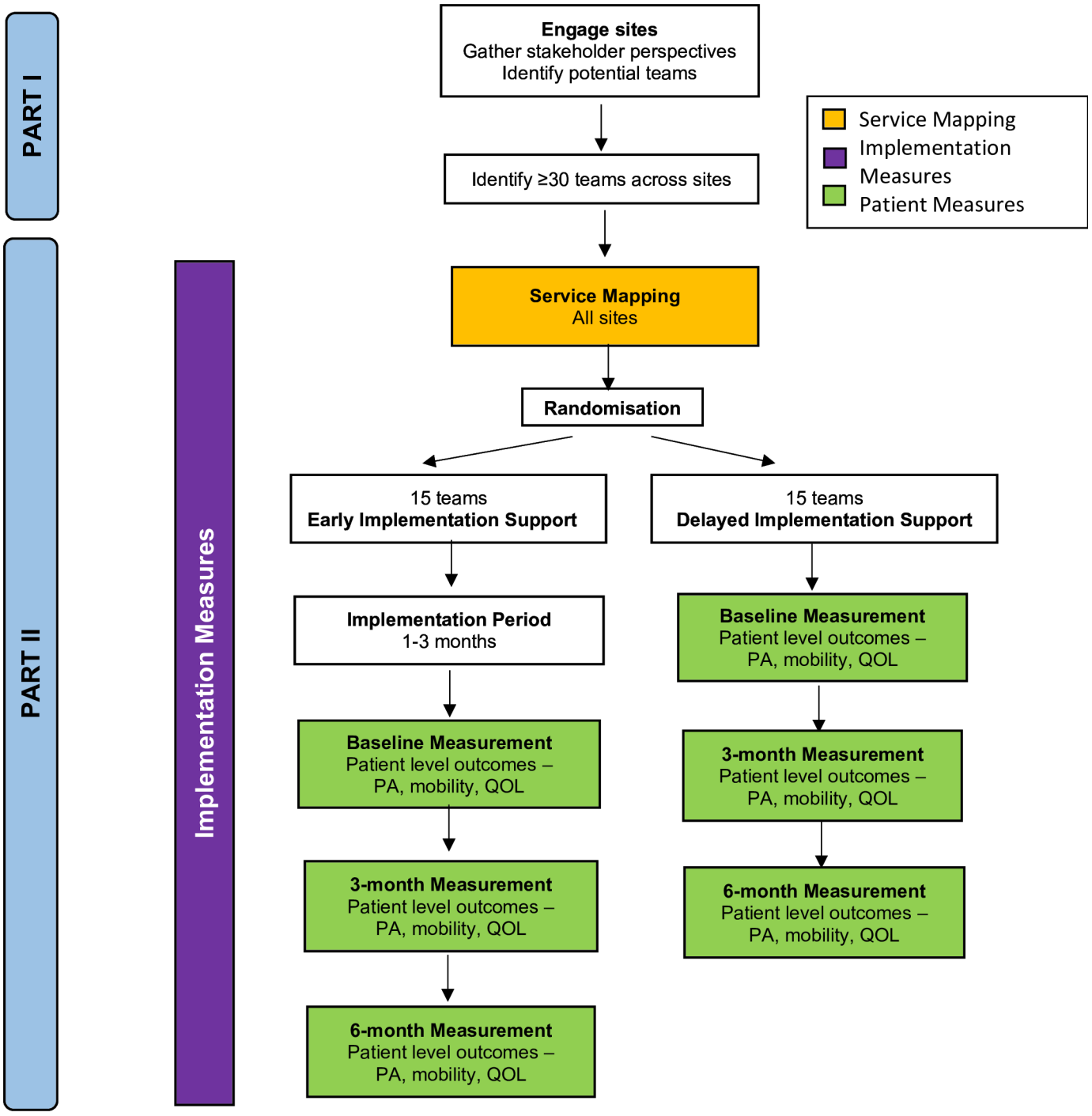

Figure 1 Promotion of Physical Activity by Health Professionals (PROMOTE-PA) study flow chart. PA, physical activity; QOL, quality of life.

- Provide informed consent and have the willingness and capacity to meet study requirements.

Patient inclusion criteria

Eligible patients will be identified by the treating health professional in each cluster. Formal informed consent and study recruitment will be undertaken by the research team. Patient participants will be eligible if they are adults (aged 18+ years) or school-aged children (aged 5–17 years) attending a participating service and who are willing to receive additional support to be more physically active; agree to complete study surveys; have no contra-indications to increase PA; and have sufficient language capabilities to respond to written or verbal questionnaires in English, Arabic or Vietnamese. Potential participants will be excluded if they have: a medical condition precluding PA/exercise; a progressive neurological disease that severely affects function; or other conditions affecting study participation for example, delirium, terminal illness, severe psychiatric disorders.

Recruitment and randomisation

Clinical teams

30 clinical teams will be recruited as clusters and randomised to either the early implementation support group (who will receive the multi-faceted implementation strategy immediately) or the delayed implementation support group (who will receive support after 3 months or once they have recruited their anticipated quota of patients). Eligible clinical teams will be identified by the Investigators in collaboration with clinical managers. The investigators will present the study protocol to the clinical team (via face-to-face or online meetings) and provide study brochures and participant information. The Head of Department or other contact person will then liaise with staff regarding interest and eligibility to participate. Health professionals who agree to participate will provide informed consent prior to the team being randomised. Health professionals who join the team during the study can also consent and participate.

Clinical teams will undertake a 'service mapping' process to tailor implementation strategies to their service. The service mapping process consists of two phases: phase I (before randomisation) and phase II (after randomisation, either immediately for the early implementation support group or after participant recruitment for the delayed implementation support group). For phase I, the research team will work with team leaders to identify team members, clinical processes and the patient journey. For phase II, the research team will work with clinical teams and managers to identify readiness for change, current PA promotion practices, barriers and facilitators to PA promotion, as well as the implementation strategies and PA promotion interventions to be delivered. A tailored implementation plan will be developed and documented for each team.

Following phase I service mapping, clinical teams will be randomised to receive the supported implementation strategy immediately or after a delay. The randomisation schedule will be generated in STATA statistical software and uploaded into Research Data Electronic Capture (REDCap) data management software. The randomisation schedule includes stratified block randomisation with randomly selected block size using two dichotomous variables: (a) anticipated number of occasions of service (services likely to provide 1–2 occasions of service per patient during study period vs services likely to provide on average 3 or more occasions of service) and (b) patient population (adults or paediatrics). When there is a team(s) to randomise, the study coordinator will enter the team into REDCap to generate group allocation. To ensure concealed allocation, research staff who are responsible for generating the schedule and uploading it into REDCap will not be involved in recruiting teams.

Patient-participants

Consecutive new patients of participating health professionals will be invited to participate by their treating health professional. Eligible patients will be provided with a written information sheet and encouraged to discuss their participation with family. The research team will then follow-up with patients by phone to seek informed consent. For participants aged 5–17 years, initial contact will be made with the parent/carer to consider the study. A child-friendly version of the study information will also be offered to children/young people who are considering participating. Written, informed consent will be given by the parent/carer for all participants aged 5–17 years, with children aged 13–17 years also able to provide assent to participate.

Interventions

As this is a hybrid type I implementation effectiveness trial, two components are being investigated; (a) evidence-based intervention (PA promotion) delivered by health professionals to their patients within their routine care with support from the research team (primary question) and (b) implementation strategies delivered by researchers to support health professionals in incorporating PA promotion into their routine care. Figure 2 provides an overview of implementation strategies and PA interventions for this study.

PA promotion intervention within routine care

The PA promotion intervention in this study is underpinned by theoretical models of behaviour change (Capability, Opportunity, Motivation-Behaviour model,[22] Self Determination Theory[23] and Social Cognitive Theory).[24] It also uses motivational interviewing, which incorporates behaviour change techniques, and has been shown to increase PA in the general population[6] as well as people with physical disabilities.[7]

The model for PA promotion in this study is informed by the '5As' Physical Activity Promotion Model.[8] The PA promotion intervention (figure 2) will be embedded into routine clinical care by health professionals and includes:

1. Assess: all health professionals will be encouraged to assess their patients' PA participation and influences on this, provide brief advice and implement one or more of the PA approaches as per that team's implementation plan.

Additional actions may include any of the following (depending on the team's patient groups, clinical setting and capacity):

2. Advise: provide advice regarding the benefits of PA and make specific recommendations on suitable opportunities.
3. Agree: collaboratively set goals and develop an action plan.
4. Assist: collaboratively identify barriers and potential solutions and set up a self-monitoring strategy.
5. Arrange: arrange referral to a community PA programme and/or the PROMOTE-PA Linkage Programme, discuss social support and follow-up.

For teams that have limited capacity to incorporate all five elements of 5As model, eligible patients will be referred by their health professional to the PROMOTE-PA

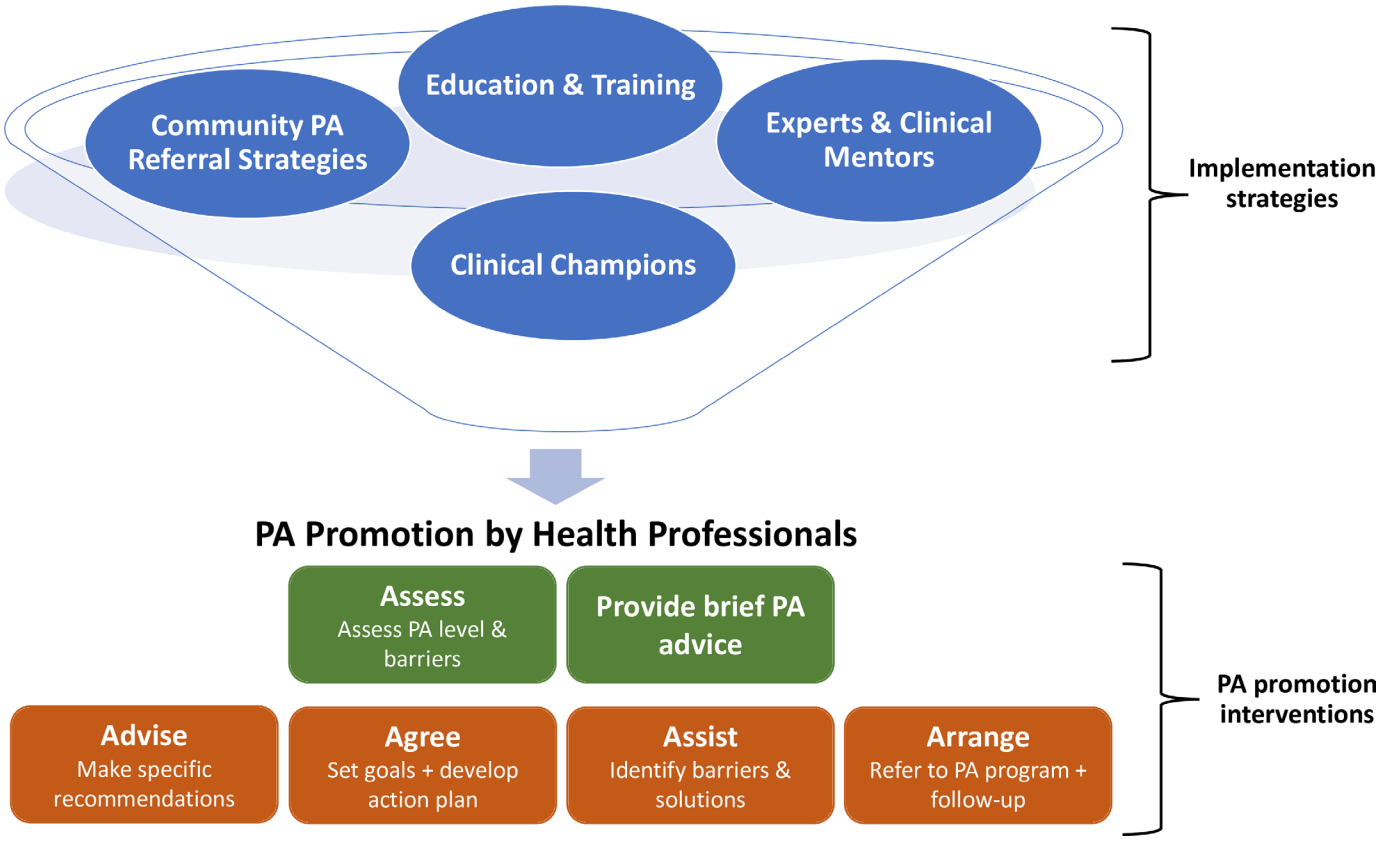

Figure 2 Overview of implementation strategies and physical activity promotion interventions to be tailored for individual clinical teams in the Promotion of Physical Activity by Health Professionals study. All teams will receive access to the online education and training implementation strategy, with the remainder to be tailored and delivered to teams as indicated. All teams will also be encouraged to deliver the 'Assess' and 'Provide brief advice' components of the physical activity promotion intervention (green boxes). The remaining physical activity promotion interventions (orange boxes) will be tailored and delivered in accordance with the implementation plan developed during the initial 'service mapping' process for each clinical team. PA, physical activity; QOL, quality of life.

Linkage Programme. The PROMOTE-PA Linkage Programme will be developed specifically for this study and delivered by trained staff within the research team. This programme will provide:

1. Assessment: an initial session of up to 1 hour from an experienced physiotherapist or exercise physiologist to identify what support they may need/want to be more active. This session may be provided via phone call or video call.
2. Tailored advice about suitable PA opportunities or ways to incorporate PA into one's day.
3. Development of an individualised plan that may include referral to local opportunities/services.
4. An optional second session to discuss the plan and provide additional support to help patients get started and stay active.

Additional PA referral options, including new models of service delivery, will also be developed where indicated to support patients transitioning from hospital-based to community-based PA opportunities. Table 1 describes the PA promotion interventions that could be delivered by health professionals in this study according to the TIDieR framework.

Implementation strategies

The implementation strategies have been selected to address barriers described in the literature as well as barriers specific to each team. Health professionals in the early implementation support group will be offered strategies to support and train them to incorporate PA promotion into their routine practice. All teams in the early implementation support group will receive access to an online resource hub, with additional strategies offered as indicated. Table 2 provides an overview of the implementation strategies to be offered in this study (tailored to each team).

Outcome measures

As a hybrid type I study, patient-level effectiveness outcomes will be measured while collecting data on implementation outcomes and determinants. All effectiveness outcomes as well as demographic information will be assessed at baseline to enable a description of patients' baseline characteristics and to obtain values to enter as covariates in the models, comparing groups at follow-up. At the time of consent, the research team member will send patients either a link to complete

Table 1 PROMOTE-PA physical activity promotion description using the Template for Intervention Description and Replication (TIDieR)

TIDieR component	PROMOTE-PA physical activity promotion by health professionals—intervention group
Why	There is strong evidence for the physical, mental, and social benefits of physical activity for people of all ages and physical abilities. Regular participation in structured physical activity including exercise, sport and active recreation can be an enjoyable way to experience the benefits of physical activity. Health professionals can have an important role in promoting physical activity and identifying suitable opportunities and recommending their patients participate in these opportunities. The WHO's Global Action Plan on Physical Activity (GAPPA) 2018–2030 recommends using the existing health workforce to promote physical activity. However, physical activity promotion is yet to be embedded into routine care for many clinical areas
What procedures	Within patients' usual management/consultation session which also addresses their clinical/impairment priorities, health professionals will be supported by the research team to deliver some of the following physical activity promotion interventions according to the 5As model of health coaching/promotion: ▶ Assessment by the treating health professional to identify their patients' current physical activity participation and influences on their physical activity participation. ▶ Delivery of brief physical activity advice using motivational interviewing techniques. ▶ Delivery of one or more of the following components (individually tailored to clinical teams): – Advise: provide specific advice regarding the benefits of physical activity, make specific recommendations and advice on suitable physical activity options, tailored to each patient. – Agree: collaboratively set goals and develop a physical activity action plan. – Assist: collaboratively identify barriers to physical activity and develop potential solutions, set up self-monitoring strategy. – Arrange: arrange referral to a community physical activity programme, arrange referral to the PROMOTE-PA Linkage Programme, explore options for social support, arrange optional follow-up. Health professionals will also be supported to invite and refer eligible patients to the PROMOTE-PA Linkage Programme to be delivered by staff within the research team. This programme will provide: ▶ Assessment: an initial session of up to 1 hour from an experienced physiotherapist or exercise physiologist to identify what support they may need/want to be more active. This session may be provided via phone call or video call. ▶ Tailored advice about suitable physical activity opportunities in the community or ways to incorporate physical activity into one's day. ▶ Development of an individualised plan to help patients increase their physical activity that includes referral to suitable physical activity opportunities/services where appropriate. ▶ An optional second session with the experienced physiotherapist or exercise physiologist to discuss the plan and provide additional support to help patients get started and stay active. Development of new physical activity programmes that support patients in transitioning from hospital-based to community physical activity programmes will also be explored as indicated
What materials	All health professionals will be provided with access to the following materials, to be delivered to patients on an individual needs basis: ▶ Online activity directory of local physical activity opportunities organised by geographical area. ▶ Online resources for health professionals and patients, for example, educational brochures for physical activity tailored to different health conditions. Additional materials will be tailored to each clinical team and could include: ▶ Referral forms/resources to suitable physical activity opportunities identified on the study-specific physical activity directory of community physical activity options. ▶ A tailored physical activity plan template
Who provided	Physical activity promotion assessment and delivery of tailored physical activity promotion components will be conducted by the treating health professional providing care in outpatient healthcare services to adults (age 18+ years) or young people (age 5–17 years). The physical activity promotion interventions will be embedded into usual care. PROMOTE-PA Linkage Programme consultations will be delivered by an experienced physiotherapist or exercise physiologist who are part of and funded by the research team
How	▶ Face-to-face or virtual initial health professional consultations with patients will be conducted and will comprise physical activity assessment and identification of relevant physical activity interventions to be tailored to each patient. ▶ Community physical activity options will be identified by the health professional searching the online physical activity directory, initially developed for a previous study and expanded for the current study. ▶ PROMOTE-PA Linkage Programme consultations will be delivered via phone or video call
Where	The intervention will be delivered to patients (young people aged 5–17 years, adults aged 18+ years) attending outpatient/community-based hospital services in five clinical districts in NSW (Sydney, Western Sydney, South Eastern Sydney, South Western Sydney Local Health Districts; Sydney Children's Hospital Network). Participating services could include physiotherapy departments, rehabilitation outpatients, geriatric/aged care outpatients and clinics involving rheumatology, endocrinology, oncology and haematology services. Similar private services may also be recruited

Continued

Table 1 Continued

TIDieR component	PROMOTE-PA physical activity promotion by health professionals—intervention group
When and how much	▲ The assessment will occur at the beginning of the intervention period as part of routine care. The duration will be determined by the treating health professional, with physical activity promotion to be embedded into routine clinical care. ▲▲ Tailored physical activity promotion interventions will be delivered to patients by the treating health professional as part of routine care. ▲▲ The PROMOTE-PA Linkage Programme will comprise an initial 1-hour session consisting of assessment and development of a tailored physical activity action plan. An optional follow-up session (30 min) will be offered
Tailoring	The health professional will work collaboratively with each patient participant to identify their needs, preferences, barriers and strengths impacting on physical activity and will include the development of physical activity recommendations for each individual. Participants will be offered referral to existing community programmes or to the PROMOTE-PA Linkage Programme, with a focus on identifying activities that participants will enjoy and are accessible. Suitable options may include attendance at a group programme, such as those indexed on the *Active and Healthy* website (https://www.activeandhealthy.nsw.gov.au/), and/or participation in sporting opportunities that cater for people with health conditions. Both face-to-face and online programmes can be considered depending on preferences. Delivery of physical activity promotion will be embedded into routine care, with frequency of consultations to be determined by the treating health professional taking into account the needs of each patient

PROMOTE-PA, Promotion of Physical Activity by Health Professionals.

the electronic survey or a paper survey. Surveys will be completed independently by participants or assisted by research staff over the telephone who are blinded to team allocation. Follow-up effectiveness outcomes will be collected via surveys at 3-month and 6-month postrandomisation. Patients will be followed up by blinded research staff if follow-up surveys are not completed within 1 week. For participants aged 5–17 years, questionnaires will be completed by the parent/proxy together with the child, or by self-report for older children/adolescents as they are able.

Primary effectiveness outcome

The primary effectiveness outcome is self-reported time (hours/week) spent in moderate-vigorous PA over the last 7 days at 3 months (primary endpoint) and 6 months from baseline. This will be measured using a modified version of the Physical Activity Vital Sign, a self-reported survey consisting of two items assessing the number of days and minutes per day spent in moderate-vigorous PA over the past 7 days.[25] For participants aged 5–17 years, this measure will be completed by proxy-report for younger children and by self-report for older children/adolescents as able. This measure has demonstrated acceptable reliability and validity among adolescents[26] and adults not currently meeting PA guidelines.[27]

Secondary effectiveness outcomes

Physical activity

additional questions assessing adherence with other aspects of the WHO PA guidelines will be collected. These questions will assess the self-reported number of days per week participating in muscle strengthening activity and in balance/functional training (participants aged 18+ years)[25] and the number of days per week active for more than 60 min using the Patient-centred Assessment and Counselling for Exercise measure (participants aged 5–17 years).[26] The three most common types of PA that participants engage in will also be recorded.

Patient-Reported Outcomes Measurement Information System

The Patient-Reported Outcomes Measurement Information System (PROMIS-29) profile V.2.1 Physical Function domain will assess physical functioning of participants aged 18+ years. The Physical Function domain includes four items, each rated on a 5-point scale. The physical function domain score will be generated (raw and T-score). The PROMIS Parent Proxy Mobility Short Form 8a will be used for participants aged 5–17 years and consists of eight mobility items rated on a 5-point scale. Preliminary evidence supports the reliability and validity of the PROMIS tool.[28]

Global perceived change in PA and mobility

Global perceived change in PA and mobility will each be assessed by a single question asking participants to rate their current PA and mobility levels now compared with 3 months ago. Each item is ranked on a 10-point scale

Table 2 Implementation strategies to be tailored to each clinical team for the PROMOTE-PA study

Implementation strategy	Mode of delivery/where/length	Content
Education and training*	Online resource hub accessible through website. All clinical teams in the intervention group will be given access to the online resource hub. Approximate total time to review all content=4 hours. Clinical teams will also be offered the option of face-to-face training	The online resources contain information, case studies and training videos supporting each of the different physical activity promotion options (coaching, referral, prescription and transition programmes). Additional resources include: ► Short educational videos/webinars presenting simulated clinical scenarios of health professionals delivering physical activity promotion targeting knowledge gaps identified in PROMOTE-PA part 1 pre-implementation study. ► Links to health professional and patient-facing resources on physical activity benefits, disease-specific considerations, examples of different physical activity options. Resources will include links to available resources, for example, Moving Medicine: https://movingmedicine.ac.uk/; WHO: https://www.who.int/health-topics/physical-activity; and copies of study developed resources
Tailored strategies to address community referral barriers	Referral strategies will be tailored and determined with each clinical team to address their specific context and the barriers they have with community referrals for their patients	Example referral strategies include: ► An Activity Directory available on the online resource hub. It provides a comprehensive geographical map and list of community physical activity opportunities across the included local health districts. ► Provide training in finding physical activity opportunities, help to develop links with physical activity providers, develop referral resources. ► Explore and develop new models of service delivery where indicated to support patients transitioning from hospital-based to community-based physical activity opportunities. These programmes could use existing staffing and partnerships with community physical activity facilities. ► Develop systems of referral to the PROMOTE-PA Linkage Programme (developed specifically for this study) and new physical activity programmes that support patients in transitioning from hospital-based to community physical activity programmes. Integrate these new referral systems into the clinical workflows for the team
Experts and clinical mentors (external to clinical team)	Mixed delivery—online and face-to-face options. Tailored to each team	Could include presentations and training (eg, how to do physical activity promotion, advice on specific considerations when promoting PA to different populations, how to navigate health professional time constraints) and Q&A sessions/ discussions on incorporating physical activity promotion into clinical practice
Clinical champions (internal member of clinical team)	Mix of face-to-face and online support delivered to clinical champions, tailored to each team	Identifying and supporting clinical champions to drive implementation of physical activity promotion into routine practice. Physical activity champions could be identified at the individual team level or site-wide depending on contextual factors. Support offered could include to identify/modify/ develop resources for their team (eg, enhancing connections with local community PA options), identify and connect with appropriate physical activity opportunities, and modify clinical assessment forms to include physical activity information to collect

*Education and training will be provided to all clinical teams in the intervention group. The remaining strategies will be offered to all clinical teams and tailored to the needs of each team as required.
PA, physical activity; PROMOTE-PA, Promotion of Physical Activity by Health Professionals.

from −5 (a lot worse) to +5 (a lot better). Global rating of change scales have adequate test–retest reliability, face validity and construct validity.[29]

EuroQOL-5D (EQ5D-5L)

Utility-based quality of life will be measured using the EQ5D-5L (adults aged 18+ years) or the EQ5D-Y Proxy

report (children and adolescents aged 5–17 years). The EQ5D-5L is a 5-item quality of life scale measuring the domains of mobility, self-care, usual activities, pain or discomfort and anxiety or depression. Each item is rated on a 5-point scale ranging from no problems to extreme problems. The EQ5D-5L also includes a visual analogue scale asking participants to rate their current health status from 0 (worst imaginable) to 100 (best imaginable). The EQ5D-5L and EQ5D-Y provide five domain scores, a visual analogue scale score (0–100) and overall health utility score.[30 31]

Strategies to include culturally and linguistically diverse patients

This study will include targeted approaches to include participants from Arabic and Vietnamese backgrounds, two common backgrounds in the Sydney region. Consultation with staff from the District Multicultural Health Services across the health districts has informed our targeted approaches to include diverse participants. Participant information, consent forms and effectiveness outcome measures will be provided to patients in their preferred language of English, Arabic or Vietnamese. Arabic and Vietnamese translations of the patient surveys will be used. Training resources for health professionals also include advice and resources for delivering PA promotion to people from diverse backgrounds.

Data analysis and management

Sample size

Recruitment of 720 patients across 30 clusters (average 24 participants per cluster) will be sufficient to detect a weekly absolute between-group difference of 75 min in moderate-vigorous PA (assuming 180 min in the early implementation support group and 105 min in the delayed implementation support group, SD=204 min). This calculation used 80% power, alpha=0.05, intraclass correlation=0.05 and allowed for a 20% dropout rate. Calculations were undertaken using clustersampsi in Stata V.16. A previous study investigating the effect of digitally enabled interventions to target PA and mobility problems postrehabilitation found a mean between-group difference of 1.8 hours/week (95% CI 0.6 to 3.0) in the walking activity subscale of the Incidental and Planned Exercise Questionnaire.[32]

Data management

Patient screening will be collected on encrypted Excel spreadsheets for each clinical team and saved on the health service password protected drive. All paper-based patient data will be entered on a password protected REDCap database[33 34] with license held by The University of Sydney. Access to this database will only include the chief investigator and required members of the research team. Patient and health professional participants will be given the option to complete surveys electronically or on paper. For electronic completion, unique survey links will be sent to participants to complete their survey directly into REDCap. For paper completion, data will be entered by a member of the research team, and a random sample of surveys (10% of completed paper surveys) will be double checked by a second member of the research team. If any errors are found a further 10% will be checked. Survey questions will use data validation in REDCap where possible.

A Data Safety and Monitoring Board has been established for this study and comprises three clinical and academic members external to the study team who will meet in the occurrence of a serious adverse event, defined as an unwanted and usually harmful outcome (eg, injurious fall, seizure, cardiac event).[35] The event may or may not be related to the intervention, but it occurs while the person is participating in the intervention for example, while they are being physically active.

Patient-level effectiveness outcomes

The planned quantitative analysis has been designed by CS and LH, overseen by the study statistician (KR). Primary analyses will be pre-planned and conducted while masked to group allocation. To account for correlation among individuals within clusters, all statistical models will use a generalised estimating equations approach with an exchangeable correlation structure.

The primary analysis will evaluate the effect of PA promotion on the self-reported PA of patients, with moderate-vigorous PA as the primary outcome. The main intention-to-treat dataset will include all patients recruited into the study irrespective of the amount of PA promotion they received. For continuous outcomes, multiple linear regression will be used with group (early implementation support vs delayed implementation support) as the primary independent variable and baseline scores as a covariate. Binary logistic regression will compare groups on dichotomous outcome measures with group as primary independent variable. We will also conduct a planned subgroup analysis for paediatric participants aged 5–17 years to investigate the effect of PA promotion on PA among children and young people.

DISCUSSION

This study tests a potentially efficient intervention to increase PA participation using the health workforce. There is strong evidence to support this intervention. The WHO's Global Action Plan on Physical Activity 2018–2030 supports PA promotion by health professionals as one of its 20 policy actions to achieve a 15% relative reduction in the global prevalence of physical inactivity by 2030.[10]

There are several minor risks in this study. The extra time required to administer the intervention could place undue stress on health professionals or compromise care to patients (participating or other). To minimise this risk, the implementation strategies and PA promotion interventions will be tailored for each team. Contamination between health professionals

in early and delayed implementation clusters could occur. We have selected a cluster trial rather than an individually randomised controlled trial to reduce this risk, however clinical staff could move between clinical teams in unforeseen circumstances. In this instance the health professional will still be welcome to participate in implementation strategies, however, they will not recruit any patients and will be asked not to share resources.

The benefits of PA are known, yet only 17% of PA studies are implementation or scale-up studies.[36] By using the hybrid type I design to test the effectiveness of the PA promotion intervention while gathering implementation data, our study will provide essential information about how this intervention can be adopted and delivered in a real-world setting. This will provide direct evidence to policymakers regarding if—and how—the intervention can be implemented and scaled up to improve PA participation.

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Acknowledgements The authors wish to thank the consumer volunteers within the Institute for Musculoskeletal Health for providing feedback on study documents. The authors also wish to thank the consumer and health professional volunteers involved in developing educational resources for patients and health professionals.

Contributors CS, LH and AT conceived the study. CS, LH, AT, LAH, MP, KH, PP, AH, MN, AB, CL, BJS, GC, GD, KW and LR received funding to conduct this study. LH designed the multi-faceted implementation strategy and evidence-based intervention with CS, AT, JNB, KP and RS with input from other authors. JNB, KP, CS, RS and LH designed the study protocol and resources with input from all authors. JNB drafted the manuscript and all authors provided critical review. All authors approved the final manuscript version. CS is the guarantor of this manuscript.

Funding This study is funded under the NHMRC 2021 Partnership Project Grant Scheme (2011157). MP and CS receive salary from an Australian National Health and Medical Research Council Fellowship. AT is supported by a University of Sydney Robinson Fellowship. BW is supported by a Research Training Programme Stipend Scholarship.

Competing interests No, there are no competing interests.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Sydney Local Health District Human Research Ethics Committee (2023/ETH01101). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. Not applicable.

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