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MOVE SMART – a feasibility study in patients with psoriasis

Submission date	Recruitment status	[X] Prospectively registered
07/10/2024	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/11/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/02/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with psoriasis are less active than others. Psoriasis can lead to heart disease and other conditions. Being more active could prevent this. Therefore, an exercise programme for people with psoriasis will be created. It is expected that being more active will improve psoriasis and reduce the risk of heart disease. Patients will likely find their well-being and physical ability improved too. However, people may still spend long periods sitting/lying down, which is also damaging to health. MOVE SMART will be developed to help people be more active and spend less time sitting down. The study aims to find out if MOVE SMART helps psoriasis and other conditions linked with psoriasis. To do that, a clinical trial will be necessary. The aim of this study will be to determine whether a clinical trial is possible or not.

Who can participate?
Patients with psoriasis aged between 18 and 60 years old

What does the study involve?
The study will last 24 weeks. All volunteers will continue with their usual treatment and have an equal chance of being in the MOVE SMART group. MOVE SMART will last for 12 weeks. Volunteers will do activities of their own choice during weeks 13-24. MOVE SMART will prompt 2 minutes of activity (only) after 30 minutes of sitting/lying down. In Workstream 1, volunteers will wear a small monitor (on their wrist/thigh) to measure activity and sitting time. At Week 1, Week 12, and Week 24, all volunteers will self-assess their psoriasis and wellbeing. The study team will assist with this. Blood will be collected at these time points using finger-prick kits. Blood pressure and body weight will also be recorded. Physical ability will be measured. In Workstream 2, feedback on MOVE SMART will be gathered, and the proposed clinical trial will be finalized in Workstream 3.

What are the possible benefits and risks of participating?
The benefits of this study will include the opportunity to follow MOVE SMART, a new lifestyle programme for patients with psoriasis. Preliminary research suggests that this may help psoriasis and other health conditions linked to psoriasis. There will be no clinic or hospital visits

required, and all study activities can be completed at home. Participation in this study will involve minimal risk, which will be managed through appropriate training and support from the study team.

Where is the study run from?
The University of Manchester will lead this research project, working in collaboration with colleagues at Manchester Metropolitan University, The University of Liverpool, and Salford Royal Hospital/Northern Care Alliance NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
June 2022 to October 2026. Recruitment into the study is expected to start in February 2025, and the study will run until November 2026.

Who is funding the study?
The study will be funded by a research grant from the National Institute for Health and Care Research (NIHR) and sponsored by The University of Manchester. Recruitment will be through an expression of interest directly to the research team.

Who is the main contact?
Dr Helen Young, The University of Manchester, helen.s.young@manchester.ac.uk

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
335248

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58898, NIHR207157

Study information

Scientific Title
MOVE SMART – a feasibility study to assess design of a randomised controlled clinical trial of a sedentary interruption intervention to improve health outcomes for patients with psoriasis

Acronym
MOVE SMART

Study objectives
A randomised clinical trial of a novel physical behaviour intervention called MOVE SMART is a feasible research proposition and acceptable to patients with psoriasis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/12/2024, North West - Greater Manchester West Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester , M1 3DZ, United Kingdom; +44 (0)207 104 8057, (0)207 104 8065; gmwest.rec@hra.nhs.uk), ref: 24/NW/0362

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Psoriasis

Interventions
The study will last 24 weeks. All volunteers will continue with their usual treatment and have an equal chance of being randomly allocated to the MOVE SMART group using a stratified randomisation procedure. MOVE SMART will last for 12 weeks. Volunteers will do activities of their own choice during weeks 13-24.

MOVE SMART: The purpose of MOVE SMART is to interrupt bouts of prolonged sedentary behaviour with light-intensity physical activity, thus reducing overall sedentary time. Its design is based upon two key points. First, WHO recommendations on physical activity together with our published data give a theoretical starting point for the amount of physical activity which may be beneficial. Second, fragmentation of sitting time every 30-minutes over a 12-hour period (09:00-21:00), is based upon recent epidemiological evidence linking a more prolonged sedentary accumulation pattern (≥30-minute bouts) with greater all-cause mortality.

MOVE SMART will be confined to a 12-hour period between 09:00 and 21:00 and will involve up to 24 2-minute bouts (48 minutes) of upright light-intensity physical activity throughout the day. An important aspect is that participants engage in light-intensity physical activities which are ADDITIONAL to their physical activity at baseline. Participants will utilise a free Mobile Application on their smartphone which will be customised to prompt physical activity following 30-minutes of sedentary behaviour. It is important to note that the Application will ONLY alert when/if a participant remains sedentary (without moving) for 30-minutes or more. The

advantage of this Application over other prompting devices is that it can be programmed to avoid alarm fatigue (borne out of iterative testing by our PPI advisors), which could lead to participants ignoring movement prompts and negatively affecting intervention compliance. On receiving an alert participants will undertake 2 minutes of light-intensity physical activity and will perform a mixture of body weight only (such as walking around the home, office, or outdoors at a steady pace, side-to-side steps, Tai Chi movements) and aided-resistance work using resistance bands (Thera-bands) which will be supplied at the start of the study. Importantly, participants will have autonomy in selecting the specific type of physical activity they wish to follow. To enhance the clarity of instruction, each recommended activity will be meticulously documented in a comprehensive illustration booklet.

Intervention Type
Behavioural

Primary outcome measure
Clinical utility in the management of psoriasis measured using the Psoriasis Area and Severity Index (PASI) self-assessment questionnaire at baseline, week 12 and week 24

Secondary outcome measures
1. Feasibility of the research processes and delivery of the intervention measured via:
1.1. Recruitment rate measured using a tally of participants recruited to study in the collected study data at baseline and week 24
1.2. Retention rate measured using a tally of participants starting and completing the study in the collected study data at week 24
1.3. Total clinical assessments completed measured using the following self-assessment questionnaires at baseline, week 12 and week 24:
1.3.1. Psoriasis Area and Severity Index (PASI)
1.3.2. Dermatology Life Quality Index (DLQI)
1.3.3. Pittsburgh Sleep Quality Index (P Sleep QI)
1.3.4. Routine Assessment of Patient Index Data 3 (RAPID3)
1.3.5. Psoriatic Arthritis Impact of Disease 12-item (PsAID12)
1.3.6. EuroQol 5-Dimension 5-Level (EQ 5D 5L)
1.4. Capillary-blood self-collection completed measured using a tally of blood collection returns received by the study team in the collected study data at baseline, week 12 and week 24
1.5. Adherence to intervention measured using an accelerometer over 1 week to count activity and sedentary time at baseline, week 6, week 12 and week 24
2. Acceptability of the intervention measured using the 5-point Likert score from the phase 1 survey at week 12
3. Acceptability of the trial processes measured using the 5-point Likert score from the phase 2 survey at week 24

Overall study start date
24/06/2022

Completion date
31/10/2026

Eligibility

Key inclusion criteria

1. Patients with Type 1 chronic plaque psoriasis (disease onset before age 40 years) with/without stable psoriatic arthritis
2. Aged 18-60 years (due to the prevalence of CVD disease in the >60s in the UK, which means that we are likely to detect greater differences in CVD risk in those <60)
3. Stable disease but measurable residual psoriasis/psoriatic arthritis
4. No treatment/dose changes for 2 months
5. High sedentary time (irrespective of level of physical activity): defined using the the Short Form International Physical Activity Questionnaire (IPAQ) as >8 hours per day

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Unable to rise from a sitting to a standing position, walk around a room (independently or aided by a walking stick, frame or trolly) whilst maintaining a steady pace (~30 steps/minute) for 2 minutes without stopping.
2. Worsening inflammatory arthritis or the presence of other significant comorbid conditions that would interfere with the ability to participate in physical activity or the study protocol, such as severe cardiovascular disease, severe chronic obstructive pulmonary disease (COPD), or any other condition as determined via the health questionnaire.
3. Regularly engaging in HIGH levels of physical activity (as defined by IPAQ) whilst spending MINIMAL time in sedentary activities during day-waking hours (as calculated by IPAQ,<6 hours per day).

Date of first enrolment
01/02/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Faculty of Biology, Medicine and Health
School of Biological Sciences
Division of Musculoskeletal and Dermatological Sciences
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Study participating centre
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Sponsor type
Hospital/treatment centre

Website
https://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/11/2027

Individual participant data (IPD) sharing plan
The (fully anonymised) datasets generated during and/or analysed during the current study will be stored in a publicly available repository (approved by The University of Manchester). Consent from participants will be obtained for this purpose.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	18/09/2024	18/11/2024	No	No