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An evaluation of the effects of a digital web-based intervention on the physical activity of people with a musculoskeletal condition

Submission date
26/05/2021

Recruitment status
No longer recruiting

Registration date
29/07/2021

Overall study status
Completed

Last Edited
26/11/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Musculoskeletal conditions affect the joints, bones and muscles. The aim of this study is to understand physical activity in people with a musculoskeletal condition, and the impact of a 12-week online physical activity programme on physical activity levels and quality of life. This study will allow for a greater understanding of the needs of people living with a musculoskeletal condition, in regards to physical activity, and how online physical activity programmes can be better designed, developed, and distributed in the future.

Who can participate?
People with a musculoskeletal condition, aged over 18 years, with the ability to read and write English and provide informed consent; who are not participating in 150 minutes (2.5 hours) or more of physical activity in a normal week. Participants should be willing to complete regular emailed surveys.

What does the study involve?
Participants will receive, over email, access to an online physical activity programme. This will either be sent straight away or three months after the start of the study – this will be decided randomly; this allows the researchers to understand the influence of the programme on physical activity (comparing those that did and did not receive access). Regardless of when participants receive access, they will be required to complete an online survey at the start of the research, once a week for 13 weeks, with a final survey at 6 months. Each online survey should take no more than 10 minutes to complete. The weekly surveys will ask participants to record their daily step count for the previous week, and their highest step count on any one day in the previous week, taken from their smartphone (if they have one) using the Pedometer α - Step Counter' app; guidance on how to do this will be provided to all participants. Participants can still take part in this study even if they do not have a smartphone.

What are the possible benefits and risks of participation?
This study will support a greater understanding of the needs of people living with a musculoskeletal condition in regards to physical activity, and how services and information can

be better designed, developed, and distributed in the future. Participants will receive an electronic copy of the final report.
The researchers do not anticipate any risks from taking part in the study. Participants will receive details of an online physical activity programme; what they do with this information and any actions that they take (or not) based on this information is up to them. Engagement with any activities mentioned within the programme is at the participant's discretion; no expectation is placed on the participant. Participants will be sent all of the information online, so no travel is required.

Where is the study run from?
London Metropolitan University (UK) - this study takes place online.

When is the study starting and how long is it expected to run for?
November 2020 to September 2022

Who is funding the study?
Versus Arthritis (UK)

Who is the main contact?
Dr Justin Webb
j.webb1@londonmet.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Justin Webb

ORCID ID
https://orcid.org/0000-0001-7637-068X

Contact details
166-220 Holloway Rd
London
United Kingdom
N7 8DB
+44 (0)20 7133 2783
j.webb1@londonmet.ac.uk

Type(s)
Scientific

Contact name
Dr Justin Webb

Contact details
166-220 Holloway Rd
London
United Kingdom

N7 8DB
+44 (0)20 7133 2783
j.webb1@londonmet.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SSPR-028

Study information

Scientific Title
A randomized control trial, with embedded process evaluation, to examine the effects of a digital web-based intervention on the physical activity of people with a musculoskeletal condition

Acronym
LondonMetVa

Study objectives
It is hypothesized that a digital web-based intervention will improve physical activity in people with musculoskeletal conditions over no intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/03/2021, London Metropolitan University – School of Social Sciences and Professions – Research Ethics Committee (London Metropolitan University, School of Social Sciences and Professions, 166-220 Holloway Road, London, N7 8DB, UK, +44 (0)20 7423 000; research@londonmet.ac.uk), ref: SSPR-028

Study design
Randomized control trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Musculoskeletal conditions

Interventions
A two-arm randomised control trial is planned with a sample of 712 participants (306 in each arm, based on an estimated decrease in those classified inactive in the intervention group from 33% to 25%; alpha of 0.05; powered to 80%). Participants will be recruited through Facebook adverts. Those that express an interest will be sent further participant information, with consent provided digitally.

Recruited participants will be randomised using simple randomisation into a control arm and an intervention arm. The intervention arm will receive a 12-week online physical activity programme consisting of 12 x 30-45 minute weekly exercise videos, with access to a Facebook group, an online forum, and a printable activity tracker; the control arm will not receive the intervention and will be sent the physical activity programme after 3 months.

The intervention and control arms will be followed up at 3 months to assess outcomes. Additional follow-up will take place, in the intervention group, at 6 months to assess the maintenance of any changes. Data collection will be web-based.

Intervention Type
Behavioural

Primary outcome(s)
1. Physical activity measured using the Sport England Active Lives questionnaire (short version) at baseline, weeks 1 through 13 and at 6 months
2. Step count measured using smartphone accelerometer data (for participants with a smartphone) using the 'Pedometer α - Step Counter' app at baseline, weeks 1 through 13 and at 6 months

Key secondary outcome(s))
1. Health-related quality of life measured using the EQ5d-5L at baseline, weeks 1 through 13 and at 6 months
2. The capability, opportunity and motivation to be physically active assessed using a bespoke six-item questionnaire at baseline, weeks 1 through 13 and at 6 months

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. People living with a musculoskeletal condition
2. Aged 18 years or over
3. Who are not active to 150 minutes a week
4. Can read English
5. Able to provide consent
6. Have an active e-mail account
7. Have a smartphone

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
403

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/08/2021

Date of final enrolment
06/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
London Metropolitan University
166-220 Holloway Road
London
United Kingdom
N7 8DB

Sponsor information

Organisation
London Metropolitan University

ROR
https://ror.org/00ae33288

Funder(s)

Funder type
Charity

Funder Name
Versus Arthritis

Alternative Name(s)
Arthritis UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Justin Webb (j.webb1@londonmet.ac.uk). Participants will provide consent for anonymised data to be used in future studies that have received all ethical, legal and regulatory approvals. Anonymised quantitative data will be available for all participants on the primary and secondary outcome measures at baseline, weeks 1 through 13 and 6 months. The data will become available following completion and write up of the research, anticipated to be June 2022 and will be made available for a period of 12 months.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/03/2023	26/11/2024	Yes	No
Participant information sheet			29/07/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes