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Protocol for ADHERE: a randomised controlled trial evaluating a digital exercise intervention with virtual supervised group exercise sessions compared to standard of care for patients receiving androgen deprivation therapy for prostate cancer

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In the UK, supervised exercise is recommended by NICE for prostate cancer patients receiving androgen deprivation therapy (ADT); however, engagement in physical activity remains limited. Although high adherence is observed during supervised exercise, it is unclear whether participants maintain activity after supervision. Barriers include treatment-related side-effects and low motivation. Digital exercise interventions that include education and behaviour change support may address these barriers and promote sustained engagement in physical activity.

The primary objective of ADHERE is to determine whether a digital exercise intervention incorporating group exercise sessions improves adherence to physical activity compared with standard of care (SOC). Secondary and exploratory objectives include assessment of health-related quality of life (HRQoL), fatigue, physical function, clinical biomarkers and participant experiences, and evaluation of cost-effectiveness.

ADHERE is a single-centre, phase III, two-arm randomised controlled trial. Prostate cancer patients within eight weeks of starting ADT and planned for radiotherapy will be recruited at The Royal Marsden NHS Foundation Trust. Participants will be randomised 1:1, stratified by ADT duration (≤ 6 months or > 6 months), to SOC alone or SOC plus the intervention. The intervention includes virtual supervised group exercise sessions delivered weekly over 26 weeks, access to exercise videos, an individualised exercise programme, educational content and “patient buddy” support.

Assessments will be conducted at baseline and three, six, and 12-months post-radiotherapy. Primary endpoint is adherence to physical activity guidelines at six months post-radiotherapy, assessed using device-based activity monitor and self-reported exercise diary. Secondary endpoint is HRQoL and will be measured using FACT-P. 160 participants (80 per arm) will be recruited allowing for 20% dropout.

ADHERE has ethical and regulatory approval and will be conducted in accordance with Good Clinical Practice. An interim analysis will be conducted, with final analyses performed following completion of all participant follow-up. Results will be disseminated via peer-reviewed publications and conferences.

Keywords

ADT; exercise; adherence; behaviour

Conflict of Interest & Ethical Approval

yes

Abstract submitters declaration

yes

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