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1. Primary Registry and Trial Identifying Number

CADAIR / PURE - Please see record for the relevant DOI (ID).

2. Date of Registration in Primary Registry

19/12/2016

3. Secondary Identifying Numbers

REC: 16/WA/0130

4. Source(s) of Monetary or Material Support

Chief Investigator and Institution

5. Primary Sponsor

Research, Business & Innovation, Aberystwyth University, Penglais, Aberystwyth, SY23 3BF
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6. Secondary Sponsor(s)

None

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9. Public Title

Do Educational digital films enhance patient COPD outcomes?

10. Scientific Title

Do patients with Chronic Obstructive Pulmonary Disease engaging with educational films in addition to Pulmonary Rehabilitation gain health-related improvements?

11. Countries of Recruitment

Wales, UK

12. Health Condition(s) or Problem(s) Studied

Chronic Obstructive Pulmonary Disease (COPD)

13. Intervention(s)

This study compares the efficacy of 10 short digital films prescribed to COPD patients alongside pulmonary rehabilitation (PR) with patients receiving PR only (usual care). The short digital films are delivered via PocketMedic, a system created by eHealth Digital Media, ltd. The films are delivered over a 10 week period, accessible online. Utilising Self-Determination Theory, the films increase patients' motivation and confidence to self-manage and show patients and practitioners talking about COPD.

The usual care control (PR), follows NICE guidelines.

14. Key Inclusion and Exclusion Criteria

All participants will be Hywel Dda UHB COPD patients who are just about to start PR. To be referred to PR in this health region, participants have to conform to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) definition of COPD. This definition is as follows: 50 years or older with at least 10 pack-years smoking history and post-bronchodilator spirometry of FEV1/FVC ratio less than 70% and FEV1 less than 80% of predicted.

Exclusions: unwilling or unable to give informed consent; those with a life-expectancy of less than 6 months, unstable cardiovascular disease, dementia, cancers other than non-melanoma skins cancer or any condition that precludes them using laptops or mobile phones (e.g. blind, deaf) and no access to computers or mobile smartphone

15. Study Type

Intervention, non-randomized, non-blinded, parallel cohort study. To assess the efficacy of PocketMedic.

16. Date of First Enrollment

20th November 2016

17. Target Sample Size

80

18. Recruitment Status

Recruiting

19. Primary Outcome(s)

Outcome: Patient engagement/adherence to digital films/PR Method of measurement: number of films watched/PR sessions attended Timepoint: Immediately after final PR session has finished

20. Key Secondary Outcomes

Outcome: Confidence to self-manage Method of measurement: Understanding COPD Timepoint: Baseline, Post-PR and 6 months Outcome: Disease Knowledge Method of measurement: Bristol COPD Knowledge Questionnaire Timepoint: Baseline, post-PR and 6 months Outcome: Service Utilization Method of measurement: number of GP visits, hospitalizations Timepoint: 6 months pre-intervention and 6 months post-intervention Outcome: Psychological self-management Method of measurement: Psychological Need Thwarting Scale (modified to COPD), Psychological Need Satisfaction in Exercise Scale (modified to COPD) and Behavioural Regulations to Exercise Questionnaire (modified to COPD). Timepoint: Baseline, post-PR and 6 months.

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