SWAT 135: Online follow-up and automatic adjustment of a physiotherapy device to optimise intervention delivery in a physiotherapy trial

Objective of this SWAT
To determine the effects of an online follow-up on optimising the delivery of the trial intervention, which is inspiratory muscle training to prevent lung complications after surgery.

Study area: To optimise the delivery of the trial intervention
Sample type: Patients
Estimated funding level needed: Low

Background
We are conducting this SWAT within the pilot phase for the NIHR-funded INSPIRE study (ISRCTN10644366), which is investigating whether a series of daily breathing exercises that aim to improve the strength and endurance of the muscles in the chest can help to reduce the chances of getting a lung complication after surgery. The SWAT uses a 2x2 factorial design to evaluate an additional virtual follow-up appointment conducted via telephone or video call with the research nurse or physiotherapist within one week of starting the inspiratory muscle training (IMT) intervention to check that participants are following the IMT protocol and training at the correct intensity; and the use of the automatic load adjusting function on the IMT device to increase the training load automatically, so that patients do not have to do this manually.

Interventions and comparators
Intervention 1: An additional virtual follow up appointment conducted via telephone or video call and the use of the automatic load adjusting function on the IMT device to increase the training load automatically.
Intervention 2: An additional virtual follow up appointment conducted via telephone or video call and manually increasing of the IMT device load.
Intervention 3: No additional virtual follow up appointment conducted via telephone or video call and the use of the automatic load adjusting function on the IMT device to increase the training load automatically.
Intervention 4: No additional virtual follow up appointment conducted via telephone or video call and manually increasing of the IMT device load.

Index Type: Optimising the delivery of the intervention for the main trial

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Change in workload (recorded on the IMT device) from baseline.
Secondary: Change in physiological marker (maximal inspiratory pressure (MIP)) from baseline;
Change in spirometry markers from baseline;
Proportion of participants following at least 80% of the planned training sessions;
Proportion of participants training at the prescribed intensity score.

Analysis plans
The primary outcome will be compared using a mixed regression model, adjusted for baseline measures. The two interventions will be fitted as fixed effects and the interaction will be examined. If the interaction is not significant at the 10% level (chosen to ensure potentially important interactions are not missed), the differences in main effects will be reported, otherwise the effect of loading method will be reported separately for the sub-groups with and without the extra online visit.

Possible problems in implementing this SWAT
Before the COVID-19 pandemic in 2020, the additional virtual follow-up appointment was intended to be a face-to-face visit in the hospital. It is difficult to know whether a "virtual" follow-up will have the same expected effect.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Dr Maria Pufulete
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Date of idea: 1/JUN/2017
Revisions made by:
Date of revisions: