Effectiveness of the eVISualisation of physical activity and pain (eVIS) intervention in Interdisciplinary Pain Rehabilitation Programs: Study Protocol for a Registry-based Randomized Controlled Clinical Trial

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Urgency
Interdisciplinary Pain Rehabilitation Programs (IPRPs) is superior to single-treatment measures for chronic pain. Despite this, effects emerge sub-optimal. More individualized treatments have been suggested to improve treatment effects. Therefore, to assist identification of individual barriers and facilitating factors to reach a beneficial physical activity level, a novel eHealth intervention eVIS, has been developed.

The eVIS-intervention
In eVIS, objectively measured physical activity (steps/day by the Fitbit Versa 2) is combined with a daily activity goal (steps/day) and daily patient reports of
- pain intensity (0-10)
- pain interference on daily activities (0-10)
- pharmaceutical consumption.
Data is collected and visualized in a web application, Pain And TRaining ON-line (PATRON) in order to provide basis for individualized treatment decisions.

Aims
To evaluate the feasibility of a subsequent registry-based randomized controlled clinical trial (R-RCT) in a pilot study and to evaluate the effectiveness of the eVIS-intervention as a supplement to IPRP in the aforementioned R-RCT.

Clinical implications
- The trial will establish evidence of the effectiveness of individualized physical activity for patients in IPRP.
- The trial contributes to introducing objective measurement methods to a clinical context.

Methods
This two-armed pragmatic multi-site R-RCT will be conducted at 15 IPRP units in Sweden. Appr. 400 patients in working age living with chronic musculoskeletal or generalized pain will be included. Random allocation to either IPRP + eVIS or to IPRP only will be performed.

Data from the first 30 participants completing the study period (6 months) will be included in a pilot study, where key feasibility outcomes (e.g., recruitment capabilities, eligibility screening, randomization, implementation, response- and compliance rate, adverse events, characteristics of outcome measures etc.) will be evaluated by the IPRP teams by ratings on a 4-point Likert scale.

In the R-RCT, the primary outcome is physical health (RAND-36) at 12 months post IPRP. Objectively measured and patient reported secondary outcomes, will be extracted from PATRON and from six national registries (e.g., data on physical activity level, emotional health, sick leave and pharmaceutical consumption).

CONSORT 2010 Flow diagram chart of study design

Read more about the eVIS-project
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