

Supplemental Material 1

Patient and public involvement (PPI) in the development, feasibility testing and evaluation of the trial reported following “Guidance for Reporting Involvement of Patients and the Public”.¹

Section and topic	Item
1: Aim Report the aim of PPI in the study	To consult and collaborate with patients, providers, administrative and management staff (together termed “stakeholders”) as research partners in the development, feasibility-testing and evaluation of the current trial.
2: Methods Provide a clear description of the methods used for PPI in the study	<p>Patients were included consecutively where it made sense and were practically possible. The patients involved had lived experience with CLBP; most of them had concrete experiences with the existing programme, whereas others had concrete experience with the integrated programme.</p> <p>All providers, administrative and management staff employed during the trial period were consecutively involved, sometimes together and sometimes in specialised groups.</p> <p>Several face-to-face meetings were held and data were collected and stored in meeting summaries and the field notes of the researcher responsible.</p> <p>In order to calculate sample size, 12 patients attending the existing programme completed the Oswestry Disability Index at the beginning and at the end of the programme.</p>
3: Study results Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	<p>PPI contributed to the trial in several ways:</p> <p>Development stage</p> <ul style="list-style-type: none"> - All stakeholders gave input to and “approved” the structure of the integrated programme. - Patients and providers suggested primary and secondary outcomes which in combination with international recommendations lead to the researchers final decision about outcome measurements . - Providers preferred Pain Self-Efficacy Questionnaire above other outcome measures when measuring the psychological outcome. - Patients read and commented on the participant information and informed consent form leading to some refinements. <p>Feasibility-testing stage</p> <ul style="list-style-type: none"> - Patient’s were involved in feasibility testing the database set-up and their comments about e.g. abbreviations and functionalities were integrated on a large scale in the final database set-up. - Patients, administrative and management staff were involved in fine-tuning administrative procedures

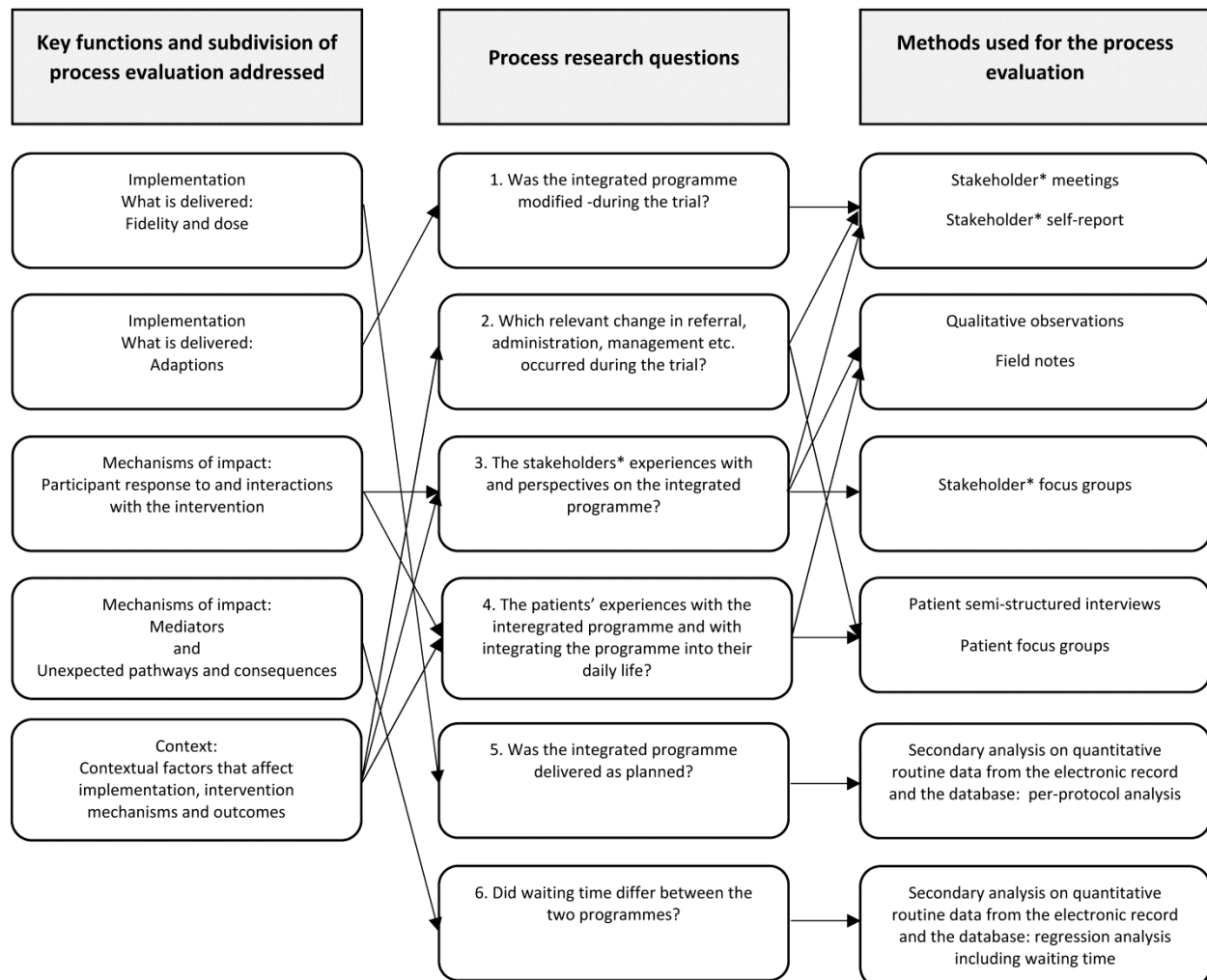
	<p>including revision of the welcome letter, e-mail wording, how to document informed consent in the electronic health record, description of the inclusion work procedure and work procedure for booking the inpatient stays. Furthermore, a person responsible for the phone calls before each booster sessions was nominated as well as a person responsible for handing out electronic tablets in order to facilitate data collection.</p> <ul style="list-style-type: none"> - Patients requested access to non-supervised aqua gymnastic to a frequency identical to that of the existing programme, a place to rest on the pre-assessment day and the day of the 26-week follow up, and a specific place to sit in the dining room. The requests were fulfilled. - The administrative and management staff were involved in the decision to overbook each integrated programme with 2-3 patients due to postponement of approximately 20% of all scheduled appointments in the existing programme. - Based on feedback from all stakeholders, the population of interest and their intended willingness to participate was deemed large enough to recruit a sufficient number of eligible patients. - Sample size was estimated based on mean ODI change score and SD from 12 patients attending the existing programme. <p>Evaluation stage</p> <ul style="list-style-type: none"> - All stakeholders were asked for feedback on the integrated programme throughout the evaluation, resulting in minor adjustments e.g. the sender of the e-mail containing the questionnaires was changed.
<p>4: Discussion and conclusions Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects</p>	<p>We believe that PPI influenced the trial in several positive ways. All stakeholders were continuously involved in the development and feasibility-testing of the trial resulting in a large degree of influence. This is considered to have had an impact on important aspects of the trial including the low number of patients not completing and considerable support from providers, administrative and management staff when trial begun.</p> <p>The consecutive inclusion of patients is seen as a strength, as it reflects the diversity of patients attending the rehabilitation centre.</p> <p>We decided not to provide PPI training for the patients, as we wanted the patients to contribute with their lived experiences as patients, and not as “professional patients”.</p> <p>No reimbursement was offered to patients; all patients asked to participate in PPI were pleased to be involved</p>

	<p>and participated as they felt they could help other patients. The management staff made it possible to prioritise involvement of providers and administrative staff despite no additional resources.</p>
<p>5: Reflections/critical perspective Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience</p>	<p>PPI was embedded as far as was possible in the development, feasibility testing and evaluation of the trial, which is considered a strength as it is expected to minimise the risk of research waste and to increase the value of the research.</p> <p>Neither the stakeholders nor the project team involved in this trial had any prior experiences with PPI in research, but everybody was interested in and curious about PPI and dedicated to, and engaged with, the task. PPI gave us new ideas, it deepened our understanding of what mattered to the patients, providers, administrative and management staff and it helped us to identify and hopefully avoid problems we may not have anticipated.</p>

1. Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *BMJ (Clinical research ed)* 2017; 358: j3453. 2017/08/05. DOI: 10.1136/bmj.j3453.

Supplemental Material 2

The key functions and subdivisions of process evaluation addressed (column 1), process research questions (column 2) and methods used for the process evaluation (column 3) (inspired by figure 23.1 and figure 23.2¹ + figure 3²).



*Stakeholders are providers, administrative and management staff.

1. Moore G. Process evaluation of complex interventions - a summary of Medical Research Councils guidance. In: Richards DAaH, I. R. (ed) *Complex Interventions in Health - An overview of research methods*. New York: Routledge, 2015, pp.222-231.
2. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ (Clinical research ed)* 2015; 350: h1258. 2015/03/21. DOI: 10.1136/bmj.h1258.