Implementing the MSK-HQ to empower patients and improve services

The MSK-Tracker study

18/12/2018

RESEARCH REFERENCE NUMBERS

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KEELE STATISTICAL ANALYSIS PLAN (SAP)

Title: The MSK Tracker single centre before & after sequential comparison study.

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Chief Investigator …Jonathan Hill……. Signature (Date) …….

Draft number ……version 1.4 **Date** ……05/12/2018…….

Declaration regarding undertaking of the analysis

Gareth McCray will be undertaking data cleaning and analysis of the study data under the guidance and supervision of Gillian Lancaster.

With reference to Protocol version …1.0 06 March 2018.

Version History Log

This section should detail the key elements of the changes to the successive versions.

Version	Date implemented	Section no. changed	Details of changes
1.1	25/05/2018	Up to section 5	Jonathan made some minor changes that were suggested by Gillian Lancaster
1.2	27/07/18	Sections 5-7, 9	Gareth updated sections 5-7, 9,10
1.3	18/09/18	As above	Gill made some edits to text and tables
1.4	05/12/2018	All	Gareth made edits to final tables and text

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Glossary of terms / Abbreviations (list) …

BMJ	British Medical Journal
BOA	British Orthopaedic Association
CATS	Clinical Assessment and Treatment Services
CI	Chief Investigator
CRF	Case Report Form
CSP	Chartered Society of Physiotherapy
CTU	Clinical Trials Unit
DoH	Department of Health
EBCD	Experience Based Co-Design
ELC	Experience Led Commissioning
e-PROM	electronic - Patient Reported Outcome Measure
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HRA	Health Research Authority
ISRCTN Trials Number	International Standard Randomised Controlled
MSK	Musculosketal
MSK-HQ	Musculoskeletal Health Questionnaire
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
PI	Principal Investigator
PPIE	Patient & Public Involvement & Engagement
PROM	Patient Reported Outcome Measure
QI	Quality Improvement
QiPP programme	Quality, Innovation, Productivity and Prevention
RCGP	Royal College of General Practitioners
RUG	Research User Group
SAE	Serious Adverse Event
SFTP	Secure File Transfer Protocol
SOP	Standard Operating Procedure
SSL	Secure Sockets Layer

1. Background and Aims

The Arthritis Research UK Musculoskeletal Health Questionnaire (MSK-HQ) is a recently validated new MSK Patient Reported Outcome Measure (PROM) that has been co-produced with patients and clinicians to measure the holistic impact of an MSK condition on a person's health. However, it is not yet known whether:

- Patients using the MSK-HQ routinely as part of their care planning, supports them to feel more involved and empowered in managing their health issues.
- Using the MSK-HQ can facilitate a more holistic care planning consultation, both in terms of the quality of patient interactions and communications with healthcare professionals.
- It is acceptable or feasible for both patients and clinicians to use the MSK-HQ as an e-PROM.

Enabling organisations to examine their aggregated MSK-HQ data at service level may also help to identify unmet need, improvement opportunities and inform MSK service and organisational developments.

The overall aim of this research is to co-design and test the feasibility and impact of implementing the MSK-HQ presented within an innovative online care planning package called the MSK-Tracker. Secondary objectives are:

a) To optimise the acceptability and utility of the MSK-Tracker as a self-management support tool for patients to use to take control of their MSK health issues and facilitate personal goal setting during MSK clinical encounters

b) To assess the feasibility and utility of the MSK-Tracker in busy consultations; the impact on the nature of the consultation when the MSK-Tracker is used and whether it supports patient enablement (feeling more in control of their MSK condition).

c) To assess its value in generating aggregated outputs and insight to inform service improvement and organisational development of MSK interface services.

2. Design

The study is using a 'before' and 'after' sequential comparison design with an iterative pilot and user testing phase in between. In addition, audio recordings of the consultation (in a sub-sample, n=40 (phase 1=20 & phase 3=20)), alongside individual clinician (n=10) and patient interviews and a feedback workshop with clinicians and patients, will explore the feasibility, and impact of implementing the MSK-Tracker within routine consultations and user experiences. The study will take place in Staffordshire Musculoskeletal Interface Service based at Haywood Hospital in Burslem, Stoke-on-Trent.

3. Study and evaluative population

Patients aged 18 years and above with an appointment to attend the Staffordshire Musculoskeletal Interface Service for an MSK pain problem will be invited to take part. Patients unable to use or access the internet will be unable to take part in this research as well as patients who do not provide informed consent for study participation and data collection. The online system will only be available in English.

Phase 1 ('Before' stage). Patients (n=120) who meet the eligibility criteria for having long-term MSK pain will consent online and complete an electronic survey shortly before their consultation. This phase will not utilise the new innovative 'MSK-Tracker' online components, in order to give a baseline comparator. Patients will complete follow-up data 2 weeks and 3 months after their clinic date and clinicians will complete a case report form (CRF) using the clinician portal. Audio recordings of approximately 20 patient consultations will examine consultation conversations and their content using discourse analysis.

Phase 2. ('Pilot stage'). Phase 2 will focus on pilot testing the MSK-Tracker components including the, pre-clinic preparation survey, clinician dashboard, summary action plan, patient's goal setting module, follow-up survey and progress charts. The study will seek to refine the processes used in phase 3, with a limited number of patients (approximately 40 patients in 2 cycles of 20) and clinicians (n=10) using the Tracker.

Phase 3 ('After' stage). Stage 3 will mirror Phase 1, ***with newly recruited patients***, except the final MSK-Tracker components will be used. As in phase 1, audio recordings of approximately 20 patient consultations will examine consultation conversations and their content. In addition, a report will be produced for the clinical managers about their service outcomes and areas of unmet need in order to inform quality improvement with a workshop planned to better understand what information services find most useful.

4. Outcomes

For each of the study Phases (1-3), taken at Baseline, Two-week follow-up and/or three month follow up (see section 9 for details on the specific measures collected at each time point).

Baseline measures:

- A range of patient self-report characteristics to be able to describe the patient population such as age, gender, ethnicity, education level, work status, health literacy, MSK pain site/condition, and episode duration. **See Tables in section 9** of this document.

Primary outcome measure:

- The Patient Enablement Index (PEI)

Secondary outcome measures:

- A number of secondary outcomes will be collected including: MSK-HQ score, Consumer Health Activation Index score, consultation experience measures, work status and impressions of the MSK-tracker system. **See Tables in section 9** for full details of these outcomes and how they will be reported.

Feasibility outcomes:

- A range of feasibility outcomes will be reported, including: numbers of participants completing each stage of the study, details around study registration, 2-week follow-up and 3-month follow-up, timing of and time taken to complete study survey components. **See Tables section 9** for full details of what feasibility information will be collected and how it will be reported.

5. Sample size

The primary outcome of this trial is the patient enablement instrument (PEI)[1] at 2 week follow up. As patients are asked to retrospectively rate the level of enablement, at the 2-week follow up, as a result of their visit to the Staffordshire Musculoskeletal Interface Service we only have a score at a single time point (and not a change score) for each group of patients in Phase 1 and Phase 3. The Patient Enablement Instrument consists of six items graded on three-point scales. It is scored between 0 and 12 and a high score represents more enablement. The sample size was generated based on that required for an independent groups two-sample t-test with a two tailed 5% significance level at 80% power. As no Minimally Clinically Important Difference (MCID) relevant to the specific context could be found for the PEI, the study is powered to find a 0.40 effect size – representative of a small to medium effect.[2] The expected SD for the population is 3.86[1] (taken from Howie et al. 1998) thus, the implied MCID between the groups would be a score of 1.55 scale points. Accordingly, the required sample is 100 in each arm. If we account for 20% dropout and missingness, the target recruitment is 120 in both phases 1 and 3.

6. Participant characteristics

Baseline characteristics for participants will be displayed in relation to the two groups of participants, i.e., those who are enrolled Phase 1 and those who are enrolled in Phase 3. Given the fact that patient groups are not randomly allocated hypothesis testing will be done comparing the groups at baseline for comparability.

See Tables in section 9 for details of which variables will be collected and how they will be reported.

7. Methods of analysis

Descriptive statistics:

For all outcomes, numerical variables will be summarised as either mean (SD) or median (IQR) depending on the skew of the distribution of the variable in question. Categorical variables will be described as frequencies and percentages.

Primary outcome measure:

A two-tailed independent sample t-test will be conducted to compare the mean PEI score in Phase 1 with that in Phase 3. An effect size, Cohen's Delta, and 95% confidence intervals will be reported for the mean difference between scores. A p-value will be reported with a significance level rate of < 5% leading to a rejection of the null hypothesis of no difference between the two groups.

Model residuals will be checked for normality, if deviation is found appropriate transformations will be made to the PEI score. Exploration of patterns of missingness will be undertaken to look for potential associates with baseline. Under the assumption of Missing at Random (MAR) missing data on the primary outcome measure will be imputed via the multiple imputation by chained equation (MICE) method[3]. Sensitivity analysis will be conducted to assess impact of the MAR assumption. Analyses will be done with missing values both ±1.55 scale points (the implied MCID) on the PEI – to model the potential effect of Missing Not at Random Bias (truncated between 0 – 12).

Secondary outcome measures:

Secondary outcome measures will be analysed via t-test. Effect sizes and 95% confidence intervals will be reported for all measures. P-values will be reported and a <5% rejection criterion will be utilised. No sensitivity analyses will be undertaken and no corrections for multiplicity will be made for the secondary outcomes.

Feasibility outcomes:

Only descriptive statistics for the feasibility outcomes will be reported. These will be counts and percentages with an appropriate denominator for each measure.

Technical details:

It is envisioned that R (current version 3.5.1) will be used for all analyses. The primary outcome will be analysed by the two study statisticians, unblinded. The statistical analyses and associated datasets will be kept in the appropriate section of the trial master file on the internal secure network.

8. References

1. Howie JG, Heaney DJ, Maxwell M, Walker JJ. A comparison of a patient enablement instrument (PEI) against two established satisfaction scales as an outcome measure of

primary care consultations. *Fam Pract*. 1998;15(2):165-171.

2. Cohen J. A Power Primer. *Psychol Bull*. 1992;112(1):155-159.
3. Buuren S, Groothuis-Oudshoorn K. mice: Multivariate imputation by chained equations in R. *J Stat Softw*. 2011;45(3).

9. Tables/Figures

Feasibility/process outcomes

Potential participants	**Phase 1 (before)**	**Phase 3 (after)**	**Total**
Number of patients **invited to take part**			
Actual participants:			
Study consent & Completed baseline survey			
Consultation **audio recording**			
Clinician completed case report form in clinic			
Patient received clinic summary action plan			
Accessed goal setting module			
Patient completed 2-week FU survey			
Patient needed a reminder email for 2-week FU survey			
Patient completed 3-month FU survey			
Patient needed a reminder email for 3-month FU survey			
Timing of survey completion:			
Time from completion of baseline survey to clinic – Mean (SD), days			
Time from clinic to 2-week FU survey completion – Mean (SD), days			
Time from clinic to 3-month FU survey completion – Mean (SD), days			
Time take to complete survey:			
Baseline survey – Mean (SD), mins*			
2-week FU survey – Mean (SD), mins*			
3-month FU survey – Mean (SD), mins*			

Baseline characteristics at Phase 1 and Phase 3

Characteristic	**Phase 1 (before)**	**Phase 3 (after)**	**Total**	**Mean (95% CI)**	**P-value**
Demographics					
Age - Mean (SD)					
Sex:					
Male					
Female					
Prefer not to say					
Missing					
Ethnicity:					
Mixed					
Asian					
Black					
White					
Other					
Prefer not to say					
Missing					
Problem Characteristics					
Pain Location(s) (percentage of respondents overall):					
Head region					
Neck					
Shoulder/upper arm					
Lower arm/wrist					
Hand(s)					
Upper back/chest/abdomen					
Lower back/pelvis					
Hip, groin, thigh					
Knee/lower leg					
Ankle/foot					
Other					
(percentage of respondents overall)					
Single site pain					
Multiple sites pain (more than one pain location)					
Has diagnosis – No. (%)					
Missing					
Problem duration:					
< 2 weeks					
2 to 4 weeks					
5 weeks to 3 months					
4 to 6 months					
7 to 12 months					
13 months to 3 years					
> 3 years					
Missing					
Previous physio for problem –No. (%)					
Missing					
Previous surgery for problem:					
No related surgery					
1 related surgery					
2 related surgeries					
3 or more related surgeries					

Missing					
Referral source:					
GP					
Self-referral					
Orthopaedic Surgeon					
Neurologist/Neurosurgeon					
Occupational Health					
Other					
Missing					
Medication usage for problem					
Missing					
Comorbidities:					
Heart disease					
High blood pressure					
Poor circulation					
Lung disease					
Diabetes					
Kidney disease					
Neurological disorder (e.g. stroke)					
Liver disease					
Cancer					
Depression					
Arthritis					
None					
Number of Comorbidities – Mean(SD)					
Independence:					
Needed assistance to fill in this questionnaire					
Considers self to have a carer					
Health Literacy					
Help needed to read instructions on pamphlets or other written material from your doctor or pharmacy – ("often" or "always") (%)					
Work & Activity					
Work status – *Working*					
Missing					
Hours missed from work in last 7 days because of problem- Mean (SD) (only working patients)					
Hours missed from work in last 7 days for other reasons- Mean (SD) (only working patients)					
Hours worked in last 7 days - Mean (SD) (only working patients)					
Joint and muscle symptoms affect your productivity while working - Mean (SD) (only working patients)					
Joint and muscle symptoms affect ability to do regular daily activities, other than work - Mean (SD) (only working patients)					
WPAI Derived Measures:					
Percent work time missed due to problem:					
Percent impairment while working due to problem					
Percent overall work impairment due to problem					
Percent activity impairment due to problem					

Outcome measures at baseline:

Overall MSK Health Status					
MSK-HQ score – Mean (SD) [score range goes from 0 – 56: higher score are milder symptoms] Reference values: • Mean MSK-HQ in National FCP pilot = 34 • Mean MSK-HQ in Community physio = 32 • Mean MSK-HQ in GP sample = 30 • Mean MSK-HQ in Ortho hip and knee waiting list sample = 27					
Patient Activation Level					
The Consumer Health Activation Index (CHAI) score – Mean (SD) [score range goes from 0-100: higher score is greater health engagement, understanding, confidence and knowledge] Reference values: • In a sample of 10,000 American adults, mean CHAI was 80.					
Low (CHAI score 0-79)					
Moderate (CHAI score 80-94					
High (CHAI score 95-100)					

Conclusion: There were no differences in patient outcomes between before and after phases

Case Report form completed by clinicians online

	Phase 1 (n=93)	Phase 3 (n=83)	Total
Review Decision			
Review			
ReviewPendingResults			
SOS Appt			
Discharged			
Treatment decision			

Injection Given			
Injection Given Opt (IM)			
Injection Given Opt (SC)			
Injection Given Opt (IA)			
Advice Given			
Treatment Declined			
No Change To Current Treatment			
No Treatment Needed			
Treatment Recommendations To GP			
New Treatment Started			
Amendments To Current Treatment			
Investigations			
Immunology			
Microbiology			
Xray			
MRI			
MRIOpt			
USound			
CTScan			
SynovialFluid			
Isotope			
Echo			
ECG			
PFT			
Haematology			
Biochemistry			
MSSU			
24HrUrine			
Capillaroscopy			
Dexa			
Neurophysiology			
Other			
Referrals			
Physio			
Podiatry			
OT			
Splinting			
Orthotics			
Chronic Pain			
Pain Clinic			
Clinical Diagnoses:			
Shoulder			
Adhesive Capsultis			
GlenohumeralOA			
ACJOA			
Subacromial Bursitis			
Rotor Cuff Impingement			
Calcific Tendomitis			
Rotator Cuff Tear			
Bicipital Tendonitis			
Rotator Cuff Tear Type			
Crystal Arthropathy			
Instability			
Other			
Hand / Wrist			
Trigger Finger			
First CMCJOA			
No dalOA			
De Quervains Tenosynovitis			
Ganglions			
Carpal Tunnel Syndrome			
Ulnar Neuritis			
Radiocarpal OA			
Other			
Elbow			
Epicondylitis			
Olecranon Bursitis			
Loose Body			
Ulnar Neuritis			
OA			
Other			
Hip			
Other			
Piriformis			
Meralgia Paraesthetica			
Adductor Enthesopathy			
Ischiogluteal Bursitis			
Trochanteric Bursitis			

OA			
Spine			
Other			
Coccydinia			
Osteoporotic Vertebral Fracture			
Spinal Stenosis			
Serious Spinal Pathology			
Chronic Low Back Pain			
Back Pain With Nerve Root Pain			
Low Back Pain			
Knee			
Other			
Shin Splints			
Pseudogout			
Pyrophosphate			
Cruciate Ligament Injury			
Collateral Ligament Injury			
Tendonitis			
Bursitis			
Bakers Cyst			
Anterior Knee Pain			
Menisceal Tear			
Mensical Degeneration			
Pateliofemoral OA			
Tibiofemoral OA			
Foot / Ankle			
Pain Arthritis			
Ligamentous Injury			
Instability			
Achilles Rupture			
Achilles Tendiopathy			
Tendinitis			
Subtelar Joint Arthritis			
Pes Planual			
Mid Foot Pain OA			
Mortons Neuroma			
Metatarsalgia			
Hallux Valgus			
First MTPJOA			
Plantar Fascitis			
Gout			
Other			
Neck			
Cervical Spondylosis			
Mechanical Neck Pain			
Brachial Neuritis			
Radiculopathy			
Non Specific Neck Pain			
Other			
Other Diagnosis			
Fibromyalgia			
Inflammatory Arthritis			
Chronic Widespread Pain			
Gout			
Hypermobility			
Polymyalgia			
Malignancy			
Other Refer			
Combined Clinic			
Orthopaedics For Surgery			
Pending Results Refer To Ortho			
Ortho For Opinion			
Other			
Other Clinical diagnosis			
Copy GP Letter To Patient			
Included In Research Trials And Education			
No Notes For Patient In Clinic			
Required during admission:			
OT Physio			
Hydrotherapy			
Splint Orthotics			
Poditry			
Specific			
Other			
Diagnostics			
USG Joint Injection			
Joint Injection			
Spinal Injection			

Two week follow up on outcome measures

	Phase 1	Phase 3	Total	Mean (95% CI)	P-value
Global change in MSK condition since my clinic appointment (5 =much better to 1 = much worse- see below) – Mean (SD)					
Global change					
5. Much better					
4. Better					
3. Same					
2. Worse					
1. Much worse					
Composite Scores					
Patient enablement index – Mean (SD) [score range is 0 to 12: higher scores = better empowerment] This items asks – "As a result of your visit to the clinic, do you feel you are:" (options - Much better=2, Better=1, Same=0) • Able to understand your illness • Able to cope with your illness • Able to keep yourself healthy • Able to cope with life • Confident about your health • Able to help yourself Reference values: In a GP sample patient mean PEI score was 4 points (1 wk later)					
MSK-HQ score – Mean (SD) Reference score at Follow-up: • Mean MSK-HQ in National FCP pilot = 41 • Mean MSK-HQ in Community physio = 42 • Mean MSK-HQ in GP sample = 37 • Mean MSK-HQ in Ortho hip and knee post-surgery = 42					
MSK-HQ BL to 2Wk change score – Mean (SD)					
Percentage of patients who achieved MCID (>= 6 points)					
The Consumer Health Activation Index (CHAI) score – Mean (SD)[a] There is no reference value yet for this score					
Low (CHAI score 0-79)					
Moderate (CHAI score 80-94					
High (CHAI score 95-100)					
The Consumer Health Activation Index (CHAI) BL-2W change score – Mean (SD)					
Percentage of patients who moved to an improved CHAI category					
Valuing Patients as Individuals Scale – Care and respect [scores range from 5 to 15: higher is better valued] The item asks if patients felt: - The clinic staff listened attentively to what they said - The clinic staff were very approachable and easy to talk to - The clinic staff treated me kindly There are no reference values yet, but this score is high					
Valuing Patients as Individuals – Understanding & engagement [scores range from 5 to 15: higher is better valued] The item asks if patients felt: - My problems were regarded as important by the therapist - The therapist answered all my questions - The therapist treated me as an intelligent human being There are no reference values yet, but this score is high					

Patient reported experience measures at 2 weeks

Patient reported experience measures at 2 weeks					
Friends and Family Test: How likely are you to recommend this service to friends and family if they need similar care or treatment?					
Extremely likely					
Likely					
Neither likely nor unlikely					
Unlikely					
Extremely unlikely					
Don't know					
Was it easy for you to get to the clinic?					
Very easy					
Easy					
Uncertain					
Not easy					
Not easy at all					
Prefer not to say					
Was the environment of the clinic okay?					

Excellent environment					
Good environment					
Uncertain					
Poor environment					
Very poor environment					
Prefer not to say					
As a result of your visit are you accessing less or more NHS care?					
Much more care					
More care					
About the same care					
Less care					
Much less care					
Prefer not to say					
How much support was available to help you make decisions about your treatment?					
Excellent support					
Good support					
Uncertain					
Poor support					
Very poor support					
Prefer not to say					
How well do you feel you now know: a) Your treatment options?					
Very well					
Well					
Uncertain					
Not well					
Not well at all					
Prefer not to say					
How well do you feel you now know: b) The pros and cons for each option?					
Very well					
Well					
Uncertain					
Not well					
Not well at all					
Prefer not to say					

Three month follow up outcome measures

	Phase 1	Phase 3	Total	Mean (95% CI)	P-value
Global change in MSK condition since my clinic appointment (5 =much better to 1 = much worse- see below) – Mean (SD)					
Global change					
5. Much better					
4. Better					
3. Same					
2. Worse					
1. Much worse					
Composite Scores					
Patient enablement index – Mean (SD) [score range is 0 to 12: higher scores = better empowerment] This items asks – "As a result of your visit to the clinic, do you feel you are:" (options - Much better=2, Better=1, Same=0) • Able to understand your illness • Able to cope with your illness • Able to keep yourself healthy • Able to cope with life • Confident about your health • Able to help yourself Reference values: In a GP sample patient mean PEI score was 4 points (1 wk later)					
MSK-HQ score – Mean (SD) Reference score at Follow-up: • Mean MSK-HQ in National FCP pilot = 41 • Mean MSK-HQ in Community physio = 42 • Mean MSK-HQ in GP sample = 37 Mean MSK-HQ in Ortho hip and knee post-surgery = 42					
MSK-HQ BL to 3 month change score – Mean (SD)					
Percentage of patients who achieved MCID (>= 6 points)					
The Consumer Health Activation Index (CHAI) score – Mean (SD)[a] There is no reference value yet for this score					
The Consumer Health Activation Index (CHAI) BL-3M change score – Mean (SD)					
Low (CHAI score 0-79)					
Moderate (CHAI score 80-94					
High (CHAI score 95-100)					

Work measures

WPAI Derived Measures:					
Percent work time missed due to problem:					
Percent impairment while working due to problem					
Percent overall work impairment due to problem					
Percent activity impairment due to problem					
Work & Activity					
Work status – *Working*					
Hours missed from work in last 7 days because of problem- Mean (SD)					
Hours missed from work in last 7 days for other reasons- Mean (SD)					
Hours worked in last 7 days for other reasons - Mean (SD)					
Joint and muscle symptoms affect your productivity while working - Mean (SD)					
Joint and muscle symptoms affect ability to do regular daily activities, other than work - Mean (SD)					

Patient Experience at 3 months

As a result of your visit are you accessing less or more NHS care? b [no baseline]					
Much more care					
More care					
About the same care					
Less care					
Much less care					
Prefer not to say					
Patient thoughts about the MSK Tracker System					
How useful did you find it?					
Very useful					
Useful					
Uncertain					
Not useful					
Not useful at all					
Prefer not to say					
How easy was it to use?					
Very easy					
Easy					
Uncertain					
Not easy					
Not easy at all					
Prefer not to say					
How well did it help you think about the issue related to the care for your joint and muscle symptoms?					
Very well					
Well					
Uncertain					
Not well					
Not well at all					
Prefer not to say					
Did it increase any stress associated with your appointment?					
Yes - increased stress a lot					
Yes - increased stress a little					
Made no difference					
No - it reduced stress a little					
No - it reduced stress a lot					

10. Appendices

Figure 1 - Consort diagram

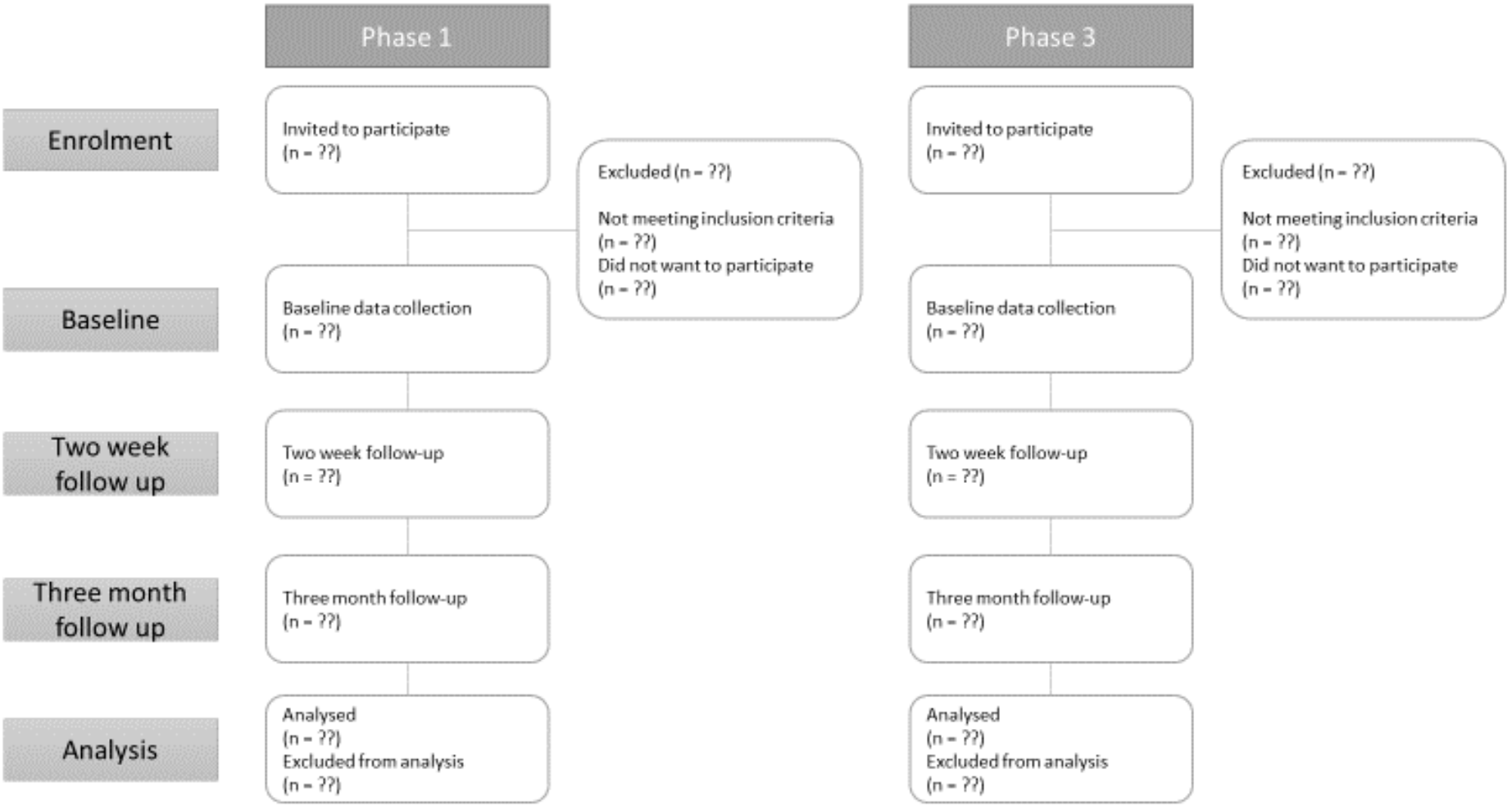

Figure 2 - Study Flow chart