A teaching trust of Brighton and Sussex Medical School

Sussex Partnership NHS Foundation Trust

Insert Study Title

RESEARCH PROTOCOL
V:30/05/18

Study Title:	Insert longest version of the study title	
Study Acronym:		
Principal Investigator:	PI name [a,b,c]	email address
Research Team:	RT name 1 [a,b,c]	email address
	RT name 2 [a,b,c]	email address
	RT name 3 [a,b,c]	email address
	RT name 4 [a,b,c]	email address
Study Sponsor:		

[a] *Institution Address*

[b] *Institution Address*

[c] *Institution Address*

For guidance on filling out the protocol see:
http://www.biomedcentral.com/bmcpublichealth/authors/instructions/studyprotocol

Contents

1 Abstract

Please overwrite these guidelines: The abstract should not exceed 350 words. Use the following headings to structure the sections **Background**, **Methods/Design**, **Discussion** (if appropriate). Don't use abbreviations or references. Include Trial registration number if one exists (see the full guidance).

2 Keywords

Please overwrite these guidelines: Three to ten keywords

3 List of abbreviations

Please overwrite these guidelines: list all.

4 Background

Please overwrite these guidelines: Write this from standpoint of researchers without specialist knowledge in the area. Include why the topic is important, literature review findings, the gaps this research intends to fill, and how this study will answer your research question.

For publication purposes, some journals would expect to see an inclusion of the Declaration of Helsinki requirement, this may require your team to have been trained in Good Clinical Practice. If this is the case it is worthwhile including this here and the suggested wording is as follows.

The researchers involved in this programme of work adhere to the 1996 version of the Declaration of Helsinki, as referred to in the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Schedule 1 parts 1.2 and 2.6: The health of our patients will be our first consideration; we shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.

4.1 Research question

Please overwrite these guidelines: provide a single clear unambiguous statement about what is being addressed. It may help to use the PICO method to formulate your question. PICO stands for:

Patient/**P**opulation - Who or What?
Intervention / Indicator- How?
Comparator/Control - What is the main alternative? (If appropriate)
Outcome - What are you trying to accomplish, measure, improve, effect?

5 Patient and Public Involvement (PPI)

5.1 Past PPI

Please overwrite these guidelines: briefly summarise past PPI activities leading up to the development of your research proposal and this current protocol.

5.2 Future PPI

Please overwrite these guidelines: describe any future planned PPI activities across the different stages of the research cycle – provide information about who, what, why and when.

6 Methods/Design

6.1 Type of study

Please overwrite these guidelines - common terms include: cohort, randomised control trial (RCT), cross-over, cross-sectional, explanatory, feasibility, internal/external pilot, explanatory, pragmatic, qualitative, quantitative, ….etc

6.2 Participants

Please overwrite these guidelines: Brief description of who the participants are.

6.2.1 Inclusion/exclusion criteria

Insert brief description and the settings and locations where the data will be collected

6.3 Aims & Objectives

Please overwrite these guidelines: provide an expansion of the research question which includes the aims/goals/hypotheses directly linked to the research question and the objectives (steps you will take to meet your aims/goals).

6.4 Recruitment and consent methods

Please overwrite these guidelines: Explaining as a minimum:

- How participants will be identified
- Who will identify participants
- Where will participants be located/how will they be contacted

- Who will make the first contact with the participant with respect to recruitment and how should this be approached
- Who will ask for consent and what is the method for this
- How will those who do not meet the criteria be handled?

6.5 Assessment process

Please overwrite these guidelines: Use the table below to name any assessments and explain who carries out the assessment, what is assessed, how the assessment is carried out and when. Include copies of any standardised assessments in the appendix.

Assessment	Carried out by	What the assessment is for	How is the assessment carried out	At what stage is the assessment carried out	Copy of assessment is in Appendix Y/N

6.6 Randomisation process & allocation concealment

Please overwrite these guidelines: include an explanation of all blinding and who (including organisation details) is carrying out the randomisation, the methodology and any restrictions (e.g. block, stratification).

Clarify the method used to implement the random allocation sequence (e.g. numbered containers or central telephone), clarify whether the sequence was concealed until interventions were assigned.

Identify who will generate the allocation sequence, who will enrol the participants, and who will assign the participants to their groups

6.7 Procedure

Please overwrite these guidelines: Briefly describe what being a participant in the study will involve.

6.8 Therapy protocols

6.8.1 Intervention procedure

Please overwrite these guidelines: Clearly describe the intervention

6.8.2 Control / comparison procedure

Please overwrite these guidelines: Describe the control/comparison clearly defining what is meant by placebo, treatment as usual or standard care for example.

6.9 Primary & Secondary Outcome Measures

Please overwrite these guidelines: clearly describe the outcomes that need to be measured to achieve your objectives; indicate the single primary outcome and as many secondary outcomes as are appropriate.

7 Data Management & Analysis

7.1 Summary of the Types of Data

Please overwrite these guidelines: Provide a list of statements of the different types of data how they will be generated, what the format will be and the scale e.g.

- Qualitative data will be generated from 20 in-depth interviews and 6 focus groups; they will be tape recorded and transcribed into Mp3 files and word documents, respectively
- Quantitative data will be generated from the completion of 200 Data Collection Booklets which are paper based, the information from each will be entered into SPSS.

7.2 Research Variables Form (RVF)

Please overwrite these guidelines: Provide a list of all data which this protocol states will be collected. If you have your own version of a RVF, please add in the appendix instead. In the 'Source/Any instructions' column, insert notes to the data collector/analyst which they need to be made aware of such as 'data likely to be skew', reverse coding needed before adding up the total score, known potential bias, …, etc.

Type of data	Variable name	Outcomes/units	Source/Any Instructions
Inclusion	Inclusion criterion 1	Yes/no	Pre screen qnre
Inclusion	Inclusion criterion 2	Yes/no	Pre screen qnre
Inclusion	Inclusion criterion … etc	Yes/no	Pre screen qnre
Exclusion	Exclusion criterion 1	Yes/no	Pre screen qnre
Exclusion	Exclusion criterion 2	Yes/no	Pre screen qnre
Exclusion	Exclusion criterion … etc	Yes/no	Pre screen qnre
Consent	Has the subject given consent freely	Yes/no	Pre screen qnre
Demographics	DOB	DD/MM/YYYY	Baseline qnre

			Need age at time=T0 in 5 year age bands [20-24], [25-39],[40-45]
Demographics	Gender	M/F/other	Baseline qnre
Demographics	Height	Meters	Baseline qnre
Demographics	Weight	KG	Baseline qnre
Demographics	BMI		Baseline qnre (BMI = Wt (kg)/H^2 (M) to be derived by the RA
Alcohol consumption	Does the participant consume alcohol	Yes/No	Baseline qnre
Alcohol consumption	Number of units consumed	units	Baseline qnre If stated that don't drink then code units = 0
MANSA score	Overall MANSA QoL score	Number	MANSA qnre
…			
Etc…			

7.3 Sample size & Power calculations

Please overwrite these guidelines: state the number of participants needed in each group and describe all calculations e.g. power, threshold of significance, effect size, minimal clinical difference, Standard Deviations, constant correlations over time, drop out rates etc.

Include a brief description of the design consideration referencing the formula used e.g. based on a cluster design using repeated measures in two groups (Machin *et al., Sample Size Tables, 3rd ed,2009).*

7.4 Planned data analysis

Please overwrite these guidelines: describe any planned analysis including baseline summaries, overall summaries of primary, secondary outcomes, newly derived variables, comparisons and methodologies (e.g. ANCOVA, logistic regression, intention-to-treat, non compliance adjustment).

If interim analyses are planned, explain what will be carried out, when, and what the results will be used for.

If new variables will be need to be derived for the analysis, define them here, verifying the units of measurement and who should carry out the transformation.

7.5 *Dummy results tables*

Please overwrite these guidelines: provide a template for any proposed data output tables that will be needed (see example)

	Intervention group		Control group	
	Time 1	Time 2	Time 1	Time 2
No. Participants	x	x	x	x
Gender (% female)	x	x	x	x
Age (Mean: SD)	x	x	x	x
QoL Score (Mean: 95% CI)	x	x	x	x
Emotion (Point estimate: SE: 95% CI)	x	x	x	x

7.6 *Data collection, entering, coding and checking process*

Please overwrite these guidelines: describe

- who will be the data manager and who will oversee this
- who will collect the data and detail the instruments/methods used and how the Data Recording Sheets(DRS)/Data Collection Booklets (DCB) will be developed;
- who will code and check the data and at what time points,
- how the DRS/DCB will be checked in the field,
- how the training needs of staff involved in data collection will be identified and addressed,
- the quality assurance checks.

Append your Research Assistant Data Management Plan.

7.7 *Missing data policy*

Please overwrite these guidelines: explain how missing data should be handled during data collection, coding and analysis.

7.8 *Potential bias*

Please overwrite these guidelines: describe any potential bias in the data identified from practice, experts or the literature and how they will be dealt with in the methodology or analysis.

7.9 *Data custodian and data ownership*

Name of data custodian: Please overwrite these guidelines - name, organisation and email address of person who is responsible for the data including access.

Name of data owner: Please overwrite these guidelines - name of organisation who owns the data.

7.10 Data quality and Standards

Please overwrite these guidelines: explain how the quality of the data will be ensured…suggested text follows -

The research team adhere to the good practice and standards principles which are set out in the Sussex Partnership Policy for Data Protection, Security and Confidentiality 2013 and the Sussex Partnership Foundation Trust Research Policy 2015. Processing of identifiable data will comply with The General Data Protection Regulation and Data Protection Act (2018).

All research will be carried out under the above standards and will be reviewed by the NHS Health Research Authority and, where applicable, an NHS Ethics Committee. The R&D departments of participating NHS Trusts will provide confirmation of capacity and capability where the HRA declare this is expected.

All members of the research team and any other individuals from collaborating Trusts or Universities involved in collecting, inputting, processing, using and sharing data will have had Information Governance Training.

Data management will be a standard item on the agenda for both research team and steering group meetings.

Data consistency and the quality of the data collection will be controlled by adhering to the Research Assistant Data Management Plan (see appendix).

7.11 Data security

Please overwrite these guidelines: explain how collected data will be kept secure, stored, archived and destroyed.

7.12 Data sharing

Please overwrite these guidelines: describe any data sharing plans and publication protocol. Check if your funding body has a data sharing or curating policy.

8 Project management

Project Team Member	Role/ Responsibilities	Contact Details

Steering Committee	Role/ Responsibilities	Contact Details

9 Ethical considerations

Please overwrite these guidelines: describe any ethical considerations that have been made e.g. around gaining informed consent, patient confidentiality and anonymity, taking measurements, ethic review comments etc.

10 Discussion of practical and operational issues

Please overwrite these guidelines: describe any known issues or results from risk assessments and how adverse events will be reported.

11 Schedule of events: Project timetable

Please overwrite these guidelines: what happens (i.e. Enrolment, eligibly screen, informed consent, procedures, allocation, intervention, assessment) during what time period (enrolment, allocation, post allocation, close-out).

12 Projected outputs and Dissemination

Please overwrite these guidelines: Describe what your outputs will be including any Intellectual Property. Also fully describe your plans for disseminating the findings of this research. Include abstracts, posters, papers, presentations to peer review journals, conferences, local or national bodies, Charities and Community Sector & Voluntary Organisations. If you aim to change NICE guidelines explain what steps you will take.

13 Plans for Translation

Please overwrite these guidelines: explain how you intend to translate the research findings into medical and nursing practice and meaningful health outcomes. Explain what will be different for patients, how things will be different and if possible within what timeframe.

14 Gantt Chart

Please overwrite these guidelines: include the study Gantt chart here state the planned study start and end dates and ensure that the following are included in addition to standard phases: PPI, data collection, data preparation, interim analysis (if appropriate), planned analysis.

15 Appendices

Please overwrite these guidelines: include all documents (draft versions are acceptable) referred to in this study including any standardised questionnaires, the Research Variables Form, Research Assistant Data Management Plan, patient information sheet, consent forms, recruitment forms, letters of agreement from collaborators, etc.

16 Amendments

Please overwrite these guidelines: describe as a minimum, any amendments to the original protocol, state reasons for changes, ethics committee involvement, date of change.

17 Competing interests

Please overwrite these guidelines: describe any competing interests (see the guidance for a full explanation).

18 Authors' contributions

Please overwrite these guidelines: In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section (see the guidance for a full explanation).

19 Acknowledgements

Please overwrite these guidelines: Please acknowledge anyone who contributed towards the article (see the guidance for a full explanation).

20 References

Please overwrite these guidelines: list all references used in this document (see the guidance for a style guide).