

Jan 2008

UK Feasibility and Adoption Form

Please read "UK Feasibility and Adoption Guidance Information" before completing this form.

SECTION 1 – CONTACT DETAILS

Chief Investigator (CI)

Name: _____ **Position:** _____

Address (including post code): _____

Telephone: _____ **Email:** _____

Lead organisation: _____

Study Coordinator

Name: _____ **Position:** _____

Address (including post code): _____

Telephone: _____ **Email:** _____

Lead organisation: _____

SECTION 2 – NETWORK INFORMATION

Please indicate which MHRN(s) you wish to run your study on

England Scotland Wales Northern Ireland

Which MHRN will lead the study coordination?

Please indicate if you have applied to or are currently hosted by another UKCRN Network (list all)

Comprehensive Clinical Research Network – please specify which CLRN

Did the study originate from one of the MHRN Clinical Research Groups? If so please specify which group:

SECTION 3 - STUDY INFORMATION

Full study title: _____

Acronym: _____

Active Status

Set-up Open Follow-up Complete

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Geographical scope

UK multi-centre International multi-centre Single centre

Primary Objectives:

Secondary Objectives:

Abstract:

Primary study design: Interventional Observational Both

Observational studies Please select

Interventional studies Please select

Interventional detail (if appropriate)
Please select

Main diagnosis: Please select

Other (please specify):

Secondary diagnosis (please specify):

Inclusion criteria

Exclusion criteria

Phase: Please select

Age limits:

SECTION 4 – SITE INFORMATION

Study setting

Primary Secondary Tertiary Social

Characteristics of care settings for recruitment – please indicate all that apply

Acute teaching hospital	<input type="checkbox"/>	Acute NHS Trust	<input type="checkbox"/>
NHS Primary Care Trust	<input type="checkbox"/>	Local Health Board (Wales)	<input type="checkbox"/>
NHS Trust providing mental healthcare	<input type="checkbox"/>	GP Practice	<input type="checkbox"/>
NHS Health Boards (Scotland)	<input type="checkbox"/>	HPSS Trusts (NI)	<input type="checkbox"/>
NHS Care Trusts	<input type="checkbox"/>	Social Care Organisations	<input type="checkbox"/>
Prisons	<input type="checkbox"/>	Independent Hospital	<input type="checkbox"/>
Educational establishment	<input type="checkbox"/>	Independent research unit	<input type="checkbox"/>

Other (please state):

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Please provide details of all site locations (MHRNs of England, Scotland, Wales and Northern Ireland & non MHRN) giving the name of the site and local investigator if applicable.

Is the study open to new centres/sites? Yes No

If yes do you want the MHRN to locate additional sites? Yes No

SECTION 5 - FUNDING AND SPONSORSHIP

Funding awarded Yes No

If no please state date decision expected:

Please complete the following as appropriate.

Funder

Name:

Grant code:

Outline application date:

Full application date:

Grant award date:

Grant start date:

Grant end date:

Amount of funding:

Service support costs/Support for Science funding required? Yes No

If yes, have costs been agreed? Yes No

Amount?

Are excess treatment costs required? Yes No

If yes, have costs been agreed? Yes No

Amount?

Please provide any additional information:

Are there any project costs that will not be covered by the funding body or through a service support or excess treatment costs agreement?

Yes No

If yes, please provide details:

Does the study receive any commercial funding or support? Yes No

If yes please provide details of support provided:

Name of study sponsor(s):

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SECTION 6 – RECRUITMENT & FOLLOW-UP

Sample size

Overall:

UK:

Description of sample size:

Planned start date for recruitment:

Actual start date (open studies):

Planned end date for recruitment:

Estimated recruitment in Year 1:

Estimated annual recruitment in subsequent years:

If recruitment targets vary between centres/sites please provide details:

Studies that are already open please provide details of recruitment to date and any shortfall along with reasons for the shortfall

Length of follow up (months):

Studies that are open or in follow-up please provide details of the follow-up target and follow-up achieved; provide reasons for any shortfall:

SECTION 7 - STATISTICS AND DATA MANAGEMENT

Statistician responsible for the study design:

Statistician responsible for study analysis:

Does your study intend to use the MHRN PsyGrid Data Entry System (DES)? Yes No

NB PsyGrid DES is available to studies running primarily in England.

If no, please provide details of the data entry system you intend to use:

SECTION 8 – STUDY MANAGEMENT

Please indicate if your project intends to have the following TRIALS ONLY



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Trial Steering Committee Yes No
Trial Management Group Yes No
Data Monitoring & Ethics Committee Yes No

OTHER STUDIES

Steering Committee Yes No
Management Group Yes No

Please provide details of any special expertise required for the study plus the academic disciplines involved:

Who will identify the potential participants?

Who will take informed consent from study participants?

SECTION 9 – ETHICS

Has MREC approval been awarded? Yes No

If no has approval been applied for? Yes No

If yes please provide:

- the MREC number for the study:
- the date of MREC approval:

SECTION 10 – CARER INVOLVEMENT (INFORMAL)

Degrees of Carer involvement

Please categorise carer involvement by ticking all relevant boxes.

Consultation (where carers are consulted with no sharing of power in decision making)

Collaboration (which involves an active on-going partnership of carers in the research process):
 researcher initiated jointly initiated carer initiated

Control (where carers design, undertake and disseminate results of a research project)

Stages of Carer Involvement

Please describe how you have involved carers and how you plan to involve carers in the following areas.

Study development:

Conduct of the study:

Dissemination of study findings:

SECTION 10 – SERVICE USER INVOLVEMENT

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Degrees of Service User involvement

Please categorise service user involvement by ticking all relevant boxes:

Consultation (where consumers are consulted with no sharing of power in decision making)

Collaboration (which involves an active on-going partnership of consumers in the research process): researcher initiated jointly initiated service user initiated

Control (where consumers design, undertake and disseminate results of a research project)

Stages of Service User Involvement

Please describe how you have involved service users and how you plan to involve service users in the following areas.

Study development:

Conduct of the study:

Dissemination of study findings:

SECTION 11 – CLINICIAN INVOLVEMENT

Please describe how clinicians or other service providers have been involved in developing or assessing the feasibility of this study:

SECTION 12 - UK MHRN INVOLVEMENT

Please state why you want to run the project on the MHRN:

Please state as fully as possible what assistance you require from the Networks:

DATE FORM COMPLETED:

The information provided in this form will be used to assess and advise on feasibility of the study to run on the MHRN. In addition, we would wish to use this information to publicise studies externally (newsletters, flyers etc) to aid study completion on time and to target. Please indicate if you are happy for the MHRN Networks to use the information in this way: Yes No

All projects hosted by the English and Scottish Networks become part of the UKCRN Portfolio database. Studies must agree to register with the UKCRN and complete the information; updating and amending throughout the course of the study. Accrual information must be uploaded to UKCRN by the study team on a monthly basis. Please indicate by checking the box that you agree to provide this information: Yes No