ISRCTN58625025 https://doi.org/10.1186/ISRCTN58625025

MRC Cardiovascular Screening and Mental Health Project: Pilot of screening intervention

Submission date	Recruitment status	[_] Prospectively registered
10/08/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2012	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr David Osborn

Contact details
UCL Department of Mental Health Sciences
Royal Free & University College Medical School
Hampstead Campus
Rowland Hill Street
London
United Kingdom
NW3 2PF
+44 (0)20 7472 6177
d.osborn@medsch.ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0301032

Study information

Scientific Title

Acronym
CaSMH

Study objectives
The intervention of a proactive nurse facilitator (PNF) will increase:
1. The rates of cardiovascular disease (CVD) risk factor screening uptake
2. Referral rates for risk reduction strategies (lifestyle and/or drug interventions) for people with severe mental illness (SMI) compared to 'treatment as usual'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 28/08/09: Camden and Islington Community Local Research Ethics Committee, letter of approval dated 05/07/2005, ref 05/Q0511/67.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease; severe mental illness

Interventions
All participating CMHTs will receive a CVD education pack for CMHT staff.
Half of participating CMHTs will be randomly assigned to receive the intervention - the services and expertise of a physical health nurse (or 'proactive nurse facilitator' - PNF) who will work within the CMHT for six months. The nurse will work proactively with existing NHS services to ensure that

a. All the CMHT's clients with SMI are offered screening for CVD risk factors and
b. That all clients who are identified as having CVD risk factors are offered appropriate risk reduction interventions (lifestyle and/or drug treatments)
Half of the CMHTs will be randomly assigned to the control group - their clients will receive 'usual care' from their GP and CMHT.
(NB: Camden & Islington Community LREC reference: 05/Q0511/67)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The proportion of service users who were (a) offered and (b) took up CVD screening.
2. The proportion of service users with CVD risk factors who were (a) offered and (b) took up appropriate referrals for risk reduction interventions (lifestyle and/or drug treatment).
3. These proportions will be compared between the intervention arm of the study (PNF services) and the control arm of the study (usual care).

Secondary outcome measures
Waiting times for CVD screening via GP or CMHT; waiting times for referrals to CVD risk reduction interventions; service user satisfaction with CVD screening and interventions; feasibility of collecting outcome data and appropriateness of outcome measures (to inform the design of future randomised controlled trials [RCTs]); economic evaluation of PNF service.

Overall study start date
15/08/2005

Completion date
31/05/2006

Eligibility

Key inclusion criteria
1. Mental health service users under the care of adult community mental health teams (CMHTs) in Camden & Islington who are participating in the exploratory trial
2. Age 18 to 75 years
3. Diagnosed with severe mental illness (i.e. schizophrenia, bipolar affective disorder, schizoaffective disorder, persistent delusional disorder, or any other non-organic chronic psychosis)
4. Able to speak and understand English or willing to have an interpreter present during trial appointments

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Evaluation phase: 150-180 service users

Key exclusion criteria
1. Age < 18 or >75 years
2. Primary diagnosis of learning disability, depressive illness, personality disorder, substance misuse (drugs or alcohol), dementia or other organic brain disease
3. Any individual whose current mental or physical state prevents them taking part in trial procedures or for whom participation would have a detrimental effect on their mental health

Date of first enrolment
15/08/2005

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Department of Mental Health Sciences
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
University College London (UK)

Sponsor details

Royal Free & University College Medical School
Hampstead Campus
Rowland Hill Street
London
England
United Kingdom
NW3 2PF

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK), Brain Sciences Initiative Trial Platform Grant Ref: G0301032 ID: 68170

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/03/2010		Yes	No