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User participation in clinical assessment and intervention

Submission date	Recruitment status	[X] Prospectively registered
25/01/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/04/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/04/2013	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
The role of a Self-Assessment and INTervention package (SAINT) in improving general mental health outcomes and reducing depressive symptoms within an intellectual disability population

Acronym
SAINT

Study objectives

Please note that as of 24/09/2008 this record has been updated. All updates can be found under the relevant section under the above update date.

Added as of 24/09/2008:
The primary hypothesis is that by providing a self-management assessment and intervention framework (SAINT), there will be an improvement in the individuals general outcomes related to mental health as described in the Health of the Nation Outcome Scales for people with Learning Disabilities (HoNOS-LD) and depressive symptoms as listed in the Glasgow Depression Scale for people with Learning Difficulties (GDS-LD).

Initial hypothesis:
The primary hypothesis is that by providing a self-management assessment and intervention framework (SAINT), used in partnership by staff and service users there will be an improvement in general outcomes as described in the Health of the Nation Outcome Scales for people with Learning Disabilities (HoNOS-LD) and depressive symptoms as listed in the Beck Depression Inventory (BDI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 24/09/2008:
Ethics approval received from the Bexley and Greenwich Research Ethics Committee on the 29th August 2008 (ref: 08/H0809/43)

Primary study design
Interventional

Study design
Randomised controlled trial (RCT)

Study type(s)
Treatment

Health condition(s) or problem(s) studied
This study looks at self assessment and management of the individuals mental health particularly depression

Interventions
Added as of 24/09/2008:
The project is in three parts:

1. Delphi consultation:
The Delphi technique is used for developing consensus in areas where there is limited evidence. The consultation aims to inform the self-questionnaire within the SAINT of predictors of increased risk to others and deteriorating mental health. Subsequent interventions to promote mental well-being will also be provided. The consultation consists of three stages for questioning and feedback:
Stage 1: initial ideas in establishing risk predictors and interventions that will form the SAINT
Stage 2: review and feedback of stage 1
Stage 3: finalising the risk predictors and interventions that will form the SAINT

2. Iterative research and pilot study:
The aim of this iterative process is to establish the predictive validity of the risk indicators chosen from the Delphi consultation best thought to reflect risk and general outcomes. This will be assessed by conducting a pilot study of between 15 - 20 service users who will have the function of pre-testing and trying out the instrument. This will provide information on the utility, reliability and validity of the self-help pack in clinical use. In doing this, the following areas will be assessed:
2.1. Development and testing of accuracy of the self-help pack
2.2. Assess the feasibility of the study
2.3. Assess whether the research protocol is realistic
2.4. Assess likely success of proposed recruitment techniques
2.5. Identify logistical problems
2.6. Estimate variability in outcomes
2.7. Collect primary data
2.8. Assess proposed data collection and analysis techniques

3. Randomised controlled trial:
The RCT will see participants being randomly allocated into two groups:
Experimental group: those receiving the SAINT
Control group: those receiving treatment as usual as defined by the host clinical area

These arrangements will not exclude either group from any ongoing treatments or assessments that form part of the host clinical areas regimen. The SAINT involves self-assessment and intervention from the service user with support where necessary. Due to the differing abilities this will be achieved with direction and support from the allocated nurse where appropriate.

The proposed treatment period will last for six months. Data will be recorded at intervals over a six month period and outcomes will be measured by the HoNOS-LD and GDS-LD prior to the introduction of the SAINT and finally after six months.

Initial interventions:
Both the experimental and control groups will receive treatment as usual that will include physical, psychological and social approaches. In the experimental group the SAINT self-management pack will be implemented. This involves self-assessment and intervention from the service user with support where necessary. Due to the differing abilities this will be achieved with direction and support from the allocated nurse where appropriate. The pack will be constructed following a Delphi consultation, which is designed to obtain consensus of expert and service user opinion.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Added as of 24/09/2008:
1. Increase in general mental health outcomes as defined within the HoNOS-LD, which has been specifically validated for use in intellectual disabilities populations and has 18 items graded for severity on a five-point scale. The HoNOS-LD is specifically aimed at people with intellectual disability regardless of degree of impairment and who have co-existing mental health needs.

2. Depressive symptoms as listed in the GDS-LD. This is a 20-item scale used to measure depressive symptoms in intellectual disability populations.

Initial primary outcome measures:
Increase in general mental health outcomes as defined within the HoNOS-LD, which has been specifically validated for use in intellectual disabilities populations. Roy et al (2002) reports that the HoNOS-LD is designed to monitor risk and vulnerability, and provides "a systematic summary of behaviours and functioning". It has 18 items graded for severity on a five-point scale. The HoNOS-LD is specifically aimed at people with intellectual disability regardless of degree of impairment and who have co-existing mental health needs.

The BDI is a 21-item scale. The highest score on each of the questions is three, the highest possible total for the whole test is sixty-three. The lowest possible score for the whole test is zero.

Key secondary outcome(s)
Accuracy of service user self perception regarding risk and mental well being and its predictive validity will be examined via the self assessment and intervention logs. This data will be supplemented with an augmented Clinical Services Receipt Inventory to examine resource issues and quality of life questionnaires to examine what role support networks and standard of living might play in self intervention and management. The 'Quality of Life Scale' is a 40-item scale conducted by interview. The items are divided into four subscales:
1. Competence/productivity
2. Self-determination/independence
3. Satisfaction
4. Social belonging/integration in the community

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Aged over 18, either sex
2. Mild intellectual disabilities as defined by an intelligence quotient [IQ] of between 50 - 70 (as measured by the Wechsler Adult Intelligence Scale - Revised [WAIS-R] and/or Wechsler Adult Intelligence Scale version three [WAIS-III]; a short IQ or WAIS will be performed where there is doubt)
3. Affective disorders in the International Classification of Diseases version 10 (ICD-10) section F30 - F39
4. Able to provide written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Service users suffering from head injury, post-development
2. Service users with an IQ of under 50
3. Service users with an IQ of over 70
4. Service users who lack capacity

Date of first enrolment
01/06/2008

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
66 Snowsfields
London
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SE1 3SS

Sponsor information

Organisation
Estia Centre (UK)

ROR
https://ror.org/015803449

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Estia Centre (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration