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Recovery Approaches in Mental Health: Evaluating the Whole Life Approach Manual (WLAM) for Therapy in Persons with Schizophrenia

Submission date	Recruitment status	[ ] Prospectively registered
12/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/07/2016	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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5963

Study information

Scientific Title
Recovery Approaches in Mental Health: Evaluating the Whole Life Approach Manual (WLAM) for Therapy in Persons with Schizophrenia

Acronym
WLAM

Study objectives
The study is a non-randomised, repeated-measures, comparative study of the Whole Life Approach Manual (WLAM). Outcomes will be assessed using both quantitative measures of health and social outcome, and qualitative measures of user perceptions and experience. The principal aim is to evaluate the effectiveness of WLAM using pre-therapy to post-therapy change in the Social Adaptation Self Assessment Scale (SASS) score in persons with schizophrenia. A comparison with a non-intervention control group will also be made. Further aims are to assess the cost of delivering WLAM, to measure adherence to the therapy and to obtain qualitative data which will illuminate which ingredients in the therapy are most successful and how the therapy can be further developed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 08/H0311/122)

Study design
Single centre non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Schizophrenia; Disease: Schizophrenia

Interventions

The Whole Life Approach Manual for Therapy is a novel therapeutic approach. It is a 15-step, 48-week, program that supports greater well being, social adaptation, life satisfaction and independence. A comparison with a non-intervention group receiving treatment as usual will also be made.

Study entry: registration only.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Social Adaptation Self-evaluation Scale (SASS). This is a self-report scale of 21 items, measured at baseline, week 24, week 48, week 60 and week 72.

Secondary outcome measures
1. Adherence with the program: adherence will be recorded by the Whole Life therapist using a five-point scale
2. Hospital Anxiety and Depression Scale (HADS), measured at baseline, week 24, week 48, week 60 and week 72
3. Health of the Nation Outcome Scales, measured at baseline, week 24, week 48, week 60 and week 72
4. Participant's perception of therapy
5. Qualitative evaluation of Whole Life Therapy
6. Social and Occupational Functioning Assessment Scale, measured at baseline, week 24, week 48, week 60 and week 72

Overall study start date
14/01/2009

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. Aged 18 - 65 years at study recruitment visit (week 0), either sex
2. A current diagnosis of schizophrenia, schizoaffective disorder, delusional disorder or schizophreniform disorder within the meaning of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV), confirmed either by the treating clinician or case record examination by a research psychiatrist
3. Current impairment in social, personal and occupational function as defined by the presence of both of a score of 35 on the SASS and a score of 75 on the Social and Occupational Functioning Assessment Scale (SOFAS)
4. Currently taking antipsychotic pharmacotherapy and with a clinical evaluation that at least 50% compliance can reasonably be expected in the forthcoming one-year period. This would typically be taken to mean that the intended dose is taken fully on 50% of days or that the full intended dose is taken on 50% of days or permutations falling between these limits.
5. Considered clinically stable by the treating psychiatrist

6. WLAM therapy is judged an appropriate therapeutic intervention by the treating psychiatrist
7. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Planned sample size: 120; UK sample size: 120

Key exclusion criteria
1. Within 180 days of the first date of diagnosis. Date of diagnosis will be taken to be the date of first diagnosis by a clinician.
2. Inpatient psychiatric attention for greater than 7 days, with any of those days being within 30 days of study entry (recruitment visit, week 0)
3. Presence of an affective psychosis which, in the opinion of the treating psychiatrist, dominates the clinical picture
4. Currently severely depressed, as defined by a score of greater than 14 on the depression subscale of the Hospital Anxiety and Depression Scale (HAD)
5. Meets DSM-IV syndromal criteria for borderline personality disorder. Potential participants with borderline personality features not meeting full criteria may be included provided that the treating psychiatrist is of the opinion that there is not syndromal borderline personality disorder.
6. Previously received WLAM for greater than 30 days
7. Received specialist therapeutic attention for a substance dependence disorder in the past 6 months. The use of illicit substances is not, in itself, exclusionary.
8. Currently subject to any legal limitation or restriction on freedom (e.g. subject to court order, probation or the Mental Health Act)
9. Currently taking exceptionally high doses of antipsychotic pharmacotherapy meaning: a total dose exceeding an aggregated 170% of BNF upper limit dosing for one or more antipsychotic drugs singly or combined, e.g., two antipsychotic drugs both being taken at 90% of their respective BNF maxima would be exclusionary
10. Currently receiving a structured psychotherapy that would continue concomitantly with WLAM therapy. Structured psychotherapy will be taken to include cognitive-behavioural therapy, interpersonal therapy, cognitive-analytic therapy, psychodynamic therapy. Therapies such as anxiety management, assertiveness training and social therapies will not be regarded as exclusionary.
11. Would be unable to undertake any free market employment because of physical disabilities directly attributable to a physical disease or handicap and that disease or handicap is permanent and irremediable

Date of first enrolment
14/01/2009

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
College Lane
Hatfield
United Kingdom
AL10 9AB

Sponsor information

Organisation
Hertfordshire Partnership Foundation NHS Trust (UK)

Sponsor details
Hertfordshire Partnership Foundation NHS Trust
99 Waverley Road
St. Albans
England
United Kingdom
AL3 5TL

Sponsor type
Hospital/treatment centre

Website
http://www.hertspartsft.nhs.uk/

ROR
https://ror.org/0128dmh12

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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