ISRCTN83240263 https://doi.org/10.1186/ISRCTN83240263

The MILESTONE study: improving transition from child to adult mental health care

Submission date
22/07/2015

Recruitment status
No longer recruiting

Registration date
23/07/2015

Overall study status
Completed

Last Edited
03/09/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The MILESTONE study focuses on the period when young people attending a children and adolescents mental health service (CAMHS) need to move on, or "transition", to an adult mental health service (AMHS), if they still require care or treatment. It is known from other research that this transition is not always properly managed and that improving the transition process can have a positive impact on the health and well-being of young people in this position. The aim of this study is to assess the impact of the different transition experiences on young people's health and well-being, and whether the process of Managed Transition has any benefits as compared to usual care.

Who can participate?
Young people aged under the regular care of a CAMHS and are reaching transition age (usually 16-18 years old)

What does the study involve?
The MILESTONE study is run in eight European countries (UK, Ireland, Belgium, Holland, France, Germany, Italy and Croatia). CAMHS in the study regions are selected to provide the young people in their care that are reaching transition age either usual care or a novel service called "Managed Transition", which includes the use of a new decision support tool, the Transition Readiness and Appropriateness Measure (TRAM). This should help with decision making and enable better transitions by identifying cases for whom transition from CAMHS to AMHS is advisable and appropriate, or who can be safely discharged or referred to a community based service. CAMHS are randomly assigned to provide the intervention of Managed Transition or usual care. The health and well-being of the young people attending these services is assessed at the start of the study and then followed-up for 24 months to see whether they transition to AMHS or are discharged or referred to some other service.

What are the possible benefits and risks of participating?
There are no benefits or risks associated with taking part in the study.

Where is the study run from?
University of Warwick (UK)

When is the study starting and how long is it expected to run for?
September 2015 to January 2019

Who is funding the study?
Seventh Framework Programme (Belgium)

Who is the main contact?
Dr Helena Tuomainen

Study website
http://www.milestone-transitionstudy.eu/

Contact information

Type(s)
Public

Contact name
Dr Helena Tuomainen

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University of Warwick
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03013595

Secondary identifying numbers
19173

Study information

Scientific Title
The effectiveness of managed transition in improving the health and social outcomes for young people transitioning from child to adult mental health care: the MILESTONE study

Acronym
MILESTONE (ManagIng the Link and Strengthening TransitiON from child to adult mental health carE)

Study objectives
Do young people reaching the transition boundary of their child and adolescent mental health service benefit from the implementation of a model of managed transition regarding their health and social outcomes, and transition to adult roles, as compared to usual care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands – South Birmingham, 24/02/2015, ref: 15/WM/0052

Study design
Both; Interventional and Observational; Design type: Process of Care, Cohort study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Topic: Children, Mental Health; Subtopic: All Diagnoses, Psychosis; Disease: Psychosis, All Diseases

Interventions
Intervention arm: The model of managed transition includes:
1. The completion of the "Transition Readiness and Appropriateness Measure" (TRAM, a standardized structured assessment) prior to the transition boundary by the child and adolescent mental health service (CAMHS) clinician, young person and parent/carer.
2. Feedback of TRAM findings to the CAMHS clinician to support decisions made regarding transition, communication with stakeholders and the transition process. Clinicians will be expected to communicate the findings to the young person and parent/carer, and, if a referral is made, to send the TRAM feedback to the adult clinician along with the referral letter.
3. The clinicians will also receive information prior to recruitment begin on the use of TRAM and the way in which it fits in with optimal transition.

The control arm: Patients, parent/carers and clinicians in the control arm will complete the TRAM prior to the transition boundary, but the clinicians won't receive any feedback from it nor any information on the benefits of using the decision support tool.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measures as of 23/01/2017:
Mental health status (need for care), measured by the use of the clinician's version of the Health of the Nation Outcome Scale for Children and Adolescents (HoNOSCA) at 15 months. The measure will be completed by a trained MILESTONE research assistant taking into account all available sources of information (including the young person, parent/carer, relevant clinician and the medical records) to ensure accuracy of data.

Previous primary outcome measures:
Mental health status (need for care), measured by the use of the clinician's version of the Health of the Nation Outcome Scale for Children and Adolescents (HoNOSCA) at baseline, 9, 15, and 24 months. The measure will be completed by a trained MILESTONE research assistant taking into account all available sources of information (including the young person, parent/carer, relevant clinician and the medical records) to ensure accuracy of data.

Secondary outcome measures

Current secondary outcome measures as of 20/06/2017:
1. Self-rated (i.e. completed by young person) mental health status (need for care), on Health of the Nation Outcome Scale for Children and Adolescents (HONOSCA) at baseline, 9, 15, and 24 months
2. Transition outcome, assessed by the Transition Related Outcome Measure (TROM) (young person, parent/carer, clinician) at 9, 15, and 24 months
3. Self-reported and parent/carer reported psychopathology, assessed by The Development and Well-being Assessment (DAWBA) (Young person, parent/carer) at baseline and 24 months and clinical diagnosis (clinician) at baseline, 9, 15 and 24 months
4. Emotional and behavioural problems, assessed by the ASEBA Youth Self Report (YSR)/Adult Self Report (ASR) questionnaires (young person) and CBCL/ABCL questionnaires (parent/carer) at baseline, 9, 15, and 24 months
5. Illness severity, assessed by Clinical Global Impression Severity scale (CGIseverity) (clinician) at baseline, 9, 15, and 24 months
6. Quality of life assessed by WHOQOLBREF (young person) at baseline, 15 and 24 months
7. Independent behaviour, assessed by Independent Behaviour During Consultation Scale (IBDCS) (young person) at baseline, 9, 15, and 24 months, if young person is a current service user
8. Illness perception, assessed by the Brief Illness Perception Questionnaire (BIPQ) (young person) at baseline and 24 months
9. Barriers to care, assessed by Barriers to Care (BtC) checklist (young person) at 9, 15, and 24 months, if young person is no longer a service user
10. Transition experience and readiness assessed by OYOF-TES – Transition Experience Scale (young person, parent/carer) completed at 9, 15 or 24 months, completed only once at the first assessment after transition
11. Adult functioning, assessed by Specific Levels of Functioning Scale (SLOF) (parent/carer) at baseline and 24 months.
12. Cost-effectiveness, assessed by EQ-5D-5L (young person) at baseline, 9, 15, and 24 months
13. Service use assessed by a MILESTONE specific Client Service Receipt Inventory (CSRI) at baseline, 9, 15, and 24 months (young person) and 9 and 24 months (parent/carer)
14. Mental health status (need for care) on clinician's version of the Health of the Nation Outcome Scale for Children and Adolescents (HoNOSCA) at baseline, 9 and 24 months. The measure will be completed by a trained MILESTONE research assistant taking into account all available sources of information (including the young person, parent/carer, relevant clinician and

the medical records) to ensure accuracy of data
All measures are completed by online survey

Previous secondary outcome measures from 23/01/2017 to 20/06/2017:
1. Self-rated (i.e. completed by young person) mental health status (need for care), on Health of the Nation Outcome Scale for Children and Adolescents (HONOSCA) at baseline, 9, 15, and 24 months
2. Transition outcome, assessed by the Transition Outcome Measure (TROM) (young person, parent/carer, clinician) at 9, 15, and 24 months
3. Self-reported and parent/carer reported psychopathology, assessed by The Development and Well-being Assessment (DAWBA) (Young person, parent/carer) and clinical diagnosis (clinician) at baseline and 24 months
4. Emotional and behavioural problems, assessed by the ASEBA Youth Self Report (YSR)/Adult Self Report (ASR) questionnaires (young person) and CBCL/ABCL questionnaires (parent/carer) at baseline, 9, 15, and 24 months
5. Illness severity, assessed by Clinical Global Impression Severity scale (CGIseverity) (clinician) at baseline, 9, 15, and 24 months
6. Quality of life assessed by WHOQOLBREF (young person) at baseline, 15 and 24 months
7. Independent behaviour, assessed by Independent Behaviour During Consultation Scale (IBDCS) (young person) at baseline, 9, 15, and 24 months, if young person is a current service user
8. Illness perception, assessed by the Brief Illness Perception Questionnaire (BIPQ) (young person) at baseline and 24 months
9. Barriers to care, assessed by Barriers to Care (BtC) checklist (young person) at 9, 15, and 24 months, if young person is no longer a service user
10. Transition experience and readiness assessed by OYOF-TES – Transition Experience Scale (young person, parent/carer) at 9 or 15 months, completed only once at the first assessment after transition
11. Adult functioning, assessed by Specific Levels of Functioning Scale (SLOF) (parent/carer) at baseline and 24 months.
12. Cost-effectiveness, assessed by EQ-5D-5L (young person) at baseline, 9, 15, and 24 months
13. Service use assessed by a MILESTONE specific Client Service Receipt Inventory (CSRI) at baseline, 9, 15, and 24 months (young person) and 9 and 24 months (parent/carer)
14. Mental health status (need for care) on clinician's version of the Health of the Nation Outcome Scale for Children and Adolescents (HoNOSCA) at baseline, 9 and 24 months. The measure will be completed by a trained MILESTONE research assistant taking into account all available sources of information (including the young person, parent/carer, relevant clinician and the medical records) to ensure accuracy of data
All measures are completed by online survey

Original secondary outcome measures:
1. Self-rated (i.e. completed by young person) mental health status (need for care), on Health of the Nation Outcome Scale for Children and Adolescents (HONOSCA) at baseline, 9, 15, and 24 months
2. Transition outcome, assessed by the Transition Outcome Measure (TROM) (young person, parent/carer, clinician) at 9, 15, and 24 months
3. Self-reported and parent/carer reported psychopathology, assessed by The Development and Well-being Assessment (DAWBA) (Young person, parent/carer) and clinical diagnosis (clinician) at baseline and 24 months
4. Emotional and behavioural problems, assessed by the ASEBA Youth Self Report (YSR)/Adult Self Report (ASR) questionnaires (young person) and CBCL/ABCL questionnaires (parent/carer) at baseline, 9, 15, and 24 months
5. Illness severity, assessed by Clinical Global Impression Severity scale (CGIseverity) (clinician) at

baseline, 9, 15, and 24 months
6. Quality of life, assessed by WHOQOLBREF (young person) at baseline and 24 months
7. Independent behaviour, assessed by Independent Behaviour During Consultation Scale (IBDCS) (young person) at baseline, 9, 15, and 24 months, if young person is a current service user
8. Illness perception, assessed by the Brief Illness Perception Questionnaire (BIPQ) (young person) at baseline and 24 months
9. Barriers to care, assessed by Barriers to Care (BtC) checklist (young person) at 9, 15, and 24 months, if young person is no longer a service user
10. Transition experience and readiness, assessed by OYOF-TES – Transition Experience Scale (young person, parent/carer) at 9 or 18 months, completed only once at the first assessment after transition
11. Adult functioning, assessed by Specific Levels of Functioning Scale (SLOF) (parent/carer) at baseline and 24 months.
12. Cost-effectiveness, assessed by EQ-5D-5L (young person) at baseline, 9, 15, and 24 months
13. Service use, assessed by a MILESTONE specific Client Service Receipt Inventory (CSRI) at baseline, 9, 15, and 27 months (young person) and 9 and 24 months (parent/carer)
All measures are completed by online survey

Overall study start date
01/02/2014

Completion date
30/06/2019

Eligibility

Key inclusion criteria
Young person inclusion:
1. Provides valid written informed consent, or assent, if below the legal age of consent
2. If age is within 1 year of reaching the transition boundary of their CAMHS during the trial recruitment period and (added 23/01/2017) in exceptional cases, not more than 3 months older than the transition boundary, if a decision about transition has not yet been made
3. Has a mental disorder defined by DSM-IV-TR, DSM-5 or ICD 10/11, or is under the regular care of CAMHS (if not yet diagnosed)
4. Has an IQ ≥ 70 as ascertained by previous standardised assessment or diagnosed by clinician, or no indication of intellectual impairment

Parent/carer inclusion:
1. Only one parent/carer per young person can be recruited into the study, the aim being to engage the same individual throughout the study. If the latter is not possible, then the aim is to involve another parent/carer
2. If the young person doesn't live with his/her biological parent/s, then his/her carer will be involved. A carer may be the legal guardian or a partner or an older adult sibling, or another individual living with and/or providing regular support to the young person
3. For young people under the legal age of consent, the parent/carer has to be the legal guardian of the young person
4. Young person consents to parent/carer participation
5. Parent/carer provides a valid written informed consent

Clinician/care provider inclusion:
1. Is responsible for the main care for young person at CAMHS (and AMHS or other relevant

service provider, if referral is made)
2. Provides a valid written informed consent

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 3000; UK Sample Size: 450; Description: UK sample size will be 150 young people +150 parents/carers+ (up to)150 clinicians + (unknown, <150) referral clinicians. So ballpark 450 - 600.This translates to the following total figures in the 8 European countries: 1000 CAMHS service users (young people), 1000 parents/carers up to 1000 CAMHS clinicians and AMHS clinicians/care provider.

Total final enrolment
844

Key exclusion criteria
Young person exclusion:
1. Does not provide valid written informed consent, or assent, if below the legal age of consent
2. Is younger than a year before the transition boundary of their CAMHS
3. Has intellectual impairment (IQ <70) as ascertained by previous standardised assessment or diagnosed by clinician (if no data on intellectual functioning are available [because it has never been assessed] then care coordinators will be asked to make a clinical judgement on intellectual impairment before baseline assessment takes place)
4. If not able to (or expected not to be able to) complete the questionnaires due to severe physical disabilities or language problems, even with assistance from family members or research assistant
5. Service user in a secure forensic institution

Parent or carer refusal or inability to participate him/herself in assessments may prevent the participation of the service user, yet this will depend on the individual country's legal and ethical situation. In the UK, young people over the age of 16 will be able to take part even if their parent /carer does not take part.

Parent/carer exclusion:
1. A parent/carer who does not live with and/or provide regular support to young person
2. Young person does not provide consent for parent/carer participation
3. Parent/carer does not provide a valid written consent
4. If not able to (or expected not to be able to) complete the questionnaires due to severe physical disabilities or language problems, even with assistance from family members or research assistant

Clinician/care provider exclusion:
1. Does not provide care for young person, or only provides intermittent care at CAMHS (and AMHS or other relevant service provider, if referral is made)
2. Does not provide a valid written informed consent

Date of first enrolment
01/09/2015

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
Belgium

Croatia

England

France

Germany

Ireland

Italy

Netherlands

United Kingdom

Study participating centre
University of Warwick
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick

Sponsor details

Gibbet Hill Road
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Sponsor type
University/education

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
There will be three kinds of papers emerging from the MILESTONE project:
Type I: the main paper, related to the primary aim/task of an individual work package.
Type II: further papers using main data set, exploring subsidiary hypotheses.
Type III: papers that explore questions of interest to individual members, or hypotheses not central to the primary objectives of the programme

Key papers linked with trial:
1. Protocol paper
2. Main trial paper on the effectiveness of managed intervention on the primary outcome comparing intervention and control arms
3. Trial paper(s) on effectiveness of managed intervention on the secondary outcomes

comparing intervention and control arms
4. Baseline predictors of good and poor transition
5. Economic evaluation of an intervention to strengthen transition from child to adult mental health care.
6. Long term outcomes of the longitudinal cohort (not the outcomes of the cRCT)

Intention to publish date
30/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Helena Tuomainen (helena.tuomainen@warwick.ac.uk)

Added 12/06/2023:
The type of data that will be shared: Baseline and follow-up data
Whether consent from participants was required and obtained: Yes
Comments on data anonymization: All data is anonymous

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	background, rationale and methodology	04/06/2018		Yes	No
Other publications	TRAM validation	23/06/2020	29/01/2021	Yes	No
Protocol article	TRAM and TROM development protocol	16/04/2020	29/01/2021	Yes	No
Protocol article	protocol	16/10/2017	29/01/2021	Yes	No
Interim results article	demographic and clinical characteristics	16/12/2021	20/06/2022	Yes	No
Results article		29/10/2021	12/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article	Demographic, clinical, and service-use characteristics results	10/02/2022	03/09/2024	Yes	No