ISRCTN35817096 https://doi.org/10.1186/ISRCTN35817096

Supporting unpaid carers when patients detained in hospital under the Mental Health Act 1983 are granted Section 17 leave from hospital

Submission date
28/03/2022

Recruitment status
No longer recruiting

Registration date
04/04/2022

Overall study status
Completed

Last Edited
02/09/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims

Friends and family members often provide substantial support to people experiencing mental health problems. Sometimes an individual's mental health problems may require them to be detained under the Mental Health Act (1983) (MHA) for assessment and/or treatment, which can mean they need to stay in hospital for a few days, weeks, months or even years at a time. It is important that during such periods the individual maintains contact with their family, friends and communities as these are helpful for their well-being. Maintaining these relationships is also important to carers.

Section 17 MHA is a provision for leave from hospital, which could include an hour in the hospital grounds, visits to local shops, or going home for a number of days, for example. This may be supervised so that the individual is accompanied by a friend or family member ('carer') or member of hospital staff, to ensure that they comply with the rules, for example around medication. However, unpaid carers are not always involved in meetings and decisions around s. 17 leave, even where they are expected to visit or to take care of someone at home during the leave period. A recent small-scale study by the research team found that carers of people on s.17 leave struggled with anxiety, low mood, feelings of guilt, difficulties in paying for activities and taking the time off work to support s.17 leave. Also, some experienced discrimination, and most felt unsupported by practitioners and under-involved in decision-making. Research into the experiences of carers of older and disabled people has similarly found that caring can often have a significant impact on their physical health, emotional and mental wellbeing, and finances.

The first part of the study used feedback from unpaid carers and mental health professionals to develop a new s.17 Standard for the Triangle of Care (guidance for NHS Mental Health Trusts on how to fully engage with carers). This second part of the study aims to test if the new s.17 Standard shows promise in practice – how it works, what it costs and if there are signs it makes a difference to carers.

Who can participate?

1. Unpaid carers of people who are admitted to hospital under s.2 or s.3 of the Mental Health

Act (1983) in participating wards/hospitals, aged 18 years or older
2. Eligible mental health practitioners working within the participating intervention wards on an invitation basis

What does the study involve?
Carers will be asked to take part in up to three interviews with the research team, each lasting no longer than 1 hour: first, very soon after the patient's admission to hospital; second, about 2 weeks after the patient's first episode of s.17 leave (if this happens); third, 6 months later (if the second interview happens). Carers who take part in the first round of interviews will only be contacted to take part in the two further interviews if the person they care for experiences s.17 leave with the carer.
Each interview involves asking some basic questions about the carer (for example, age, gender, relationship to the person they care for, services they access or receive), and a series of questions about their experience of caring, their knowledge and experience of s.17 leave and the support they received or would have liked to receive.
Eligible mental health practitioners will be invited to take part in either interviews or workshops on two occasions, each lasting no longer than one hour; the first shortly after implementation of the S.17 standard in their ward and the second approximately twelve months after implementation. Practitioners will be asked to share their experiences of the implementation and use of the s.17 standard, barriers and facilitators to using the standard, and suggestions for further refinement of the standard.

What are the possible benefits and risks of participating?
Carers' views will help the research team to understand how, if at all, the s.17 Standard affects their experiences when the person they care for is granted s.17 leave from hospital to try to improve support for carers before, during and after s.17 leave. Carers will also be given a £20 shopping voucher after each interview as a thank you for their time.Practitioner views will help the research team to understand the benefits and challenges in implementing the s.17 Standard in practice which will hopefully help to develop the Standard into a more effective tool for practice. It is possible that talking about caring experiences may be distressing. Carers may decline to answer certain questions, take a break, or leave the interview at any time and the research team will provide contact details for support organisations. There are no anticipated risks to practitioners.

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

When is the study starting and how long is it expected to run for?
November 2021 to May 2023

Who is funding the study?
National Institute for Health Research School for Social Care Research (NIHR SSCR) (UK)

Who is the main contact?
Prof. Martin Webber
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Contact information

Type(s)
Scientific

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Prof Martin Webber

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
300813

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 51277, IRAS 300813, NIHR School for Social Care Research at London School of Economics and Political Sciences Grant Code 102645/CM/UYYB-P154

Study information

Scientific Title
Section 17 Leave: supporting unpaid carers

Study objectives
This study is exploratory in nature. Phase 1 of the study gathered stakeholder views to inform the development of a Section 17 Leave Standard of Care Protocol. Phase 2 of the study is a feasibility pilot to check whether there are any signals of efficacy for the Section 17 Leave Standard of Care which would indicate a full-scale feasibility trial is warranted. As such, the study would be hypothesis-generating in nature rather than hypothesis testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 08/12/2021, West of Scotland REC 3 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0212; WosRec3@ggc.scot.nhs.uk), ref: 21/WS/0156

Study design
Non-randomized; Both; Design type: Process of Care, Complex Intervention, Qualitative

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Mental health

Interventions
Design:
In this feasibility study, the researchers will use a non-randomised controlled study design to test the s.17 standard for signals of efficacy. This will enable them to explore the indicative outcomes for carers of patients in intervention wards in comparison to carers of patients in control wards, to help the researchers to determine if it is worthwhile to proceed to a feasibility trial. Additionally, this design will enable them to evaluate how the s.17 standard is implemented in diverse contexts; how it is experienced by practitioners, managers, RCs and carers; and what its indicative costs might be.

Setting:
The study will be conducted across a number of sites to ensure a diversity of experiences in urban and rural settings in different locations in England. Each site will select wards to implement the new s.17 standard (intervention wards) and wards that will continue with business as usual (control wards); this will be determined through consultation between practitioners and the research team.

Sample:
The end-point is full data on 30 carers who have experience of leave under s.17 with the person they are caring for during an inpatient admission, in both the test and comparison groups (30 per group), as this is widely viewed as sufficient for an initial test of a new intervention. As the recruitment of carers will be conducted prior to s.17 leave being granted, and it will not be possible to know for certain if leave with a carer will be provided during the admission, the researchers will need to over-recruit carers to ensure a sufficient sample. Data from one trust showed that 90% of s.17 leave was for less than 24 hours. While some of this may be home leave, a high proportion is likely to be in hospital grounds. It is therefore estimated that 50% of carers recruited for the study will experience home leave under s.17 during the admission. Assuming a 25% drop-out or loss-to-follow-up, the researchers will recruit 80 carers of people detained under the MHA in both the test and comparison groups to participate in the study.

Recruitment procedures:
Carers will be identified at the point at which their loved one is admitted to hospital under s.2 or s.3 MHA or shortly afterwards by staff on inpatient wards. They will be provided with information about the study and asked if they are willing to be contacted by a researcher to

explain what the study involves, answer any questions and complete the screening process. The researcher will contact those who consent to being contacted to discuss the study, invite questions and arrange a date/time for the first interview if the carer wishes to take part.

Study procedures:
Prior to the first interview written consent will be obtained via a consent form or verbal consent will be recorded over the telephone. Carers may take part in up to three interviews. All carer participants will take part in a structured telephone interview at baseline. This will be soon after the admission of the person they provide care for, but before the first period of s.17 leave during that admission. The researchers will ask inpatient staff, care coordinators and/or carers to inform us when the first period of s.17 leave with a carer occurs, so that they can conduct a follow-up structured telephone interview 2 weeks after the end of this to collect outcome data. The length of time from baseline to follow-up will be recorded and controlled for in the analysis. A third structured telephone interview will be held 6 months after baseline to collect final outcome data. Where patients do not receive s.17 leave with a carer during the period of the study, carers will only take part in the first (baseline) interview. Interviews can be conducted by phone or by video conferencing (e.g. MS Teams). Face-to-face interviews will be conducted with carers unable to participate in a telephone or video interview if Covid restrictions allow. Face-to-face interviews would be held in Covid-secure settings e.g. well-ventilated meeting rooms in Trust/hospital buildings. Participants will be offered a £20 shopping voucher to thank them for their time for each interview completed. The same procedures will be followed in the test and comparison groups.

Analysis:
Recruitment and retention rates, sample socio-demographic characteristics and baseline measures will be described using descriptive statistics. Inferential statistics such as paired t-tests for normally distributed continuous variables will be used to evaluate change in outcomes from baseline to 2 weeks following home leave and at 6 months after baseline. Non-parametric statistics will be used to evaluate change in skewed or categorical variables as required. The analysis will be conducted separately for the test and comparison groups. Finally, a linear regression model will be constructed for the primary outcome to assess the respective contribution of group allocation, sociodemographic and other characteristics to change at 2 weeks after leave and at 6-months follow-up.

Process evaluation:
The researchers will use multiple methods to also explore how mental health services implement the s.17 standard and the experience of this for practitioners, managers, RCs and carers.

Firstly, a qualitative component will be added to all carers' interviews at 2-week follow-up to explore their experience of the s.17 leave. The researchers will ask them to discuss the support provided; their experience and perception of the impact of the support; challenges with the provision of the support; and their view on any improvements which could be made to improve its effectiveness.

Secondly, the researchers will set up implementation groups across the intervention wards to lead the implementation of the s.17 standard in their respective sites. The implementation groups from each site will be introduced and encouraged to share difficulties, solutions and experiences during the study so that they may learn from one another. The researchers will also meet with the groups separately on two occasions to check progress with implementation and identify what it is possible to implement without additional resource. Managers, practitioners and RCs from the intervention wards will be interviewed twice; once 3 months after the site

commences using the s.17 standard to discuss any initial teething problems, and again approximately 12 months later to reflect on any implementation issues, barriers and facilitators to using the s.17 standard, and any suggestions for further refinement. This will be a further check on what the s.17 standard should include and what the barriers and facilitators to achieving this are likely to be. Interviews and/or workshops will likely be held remotely, either by telephone (for individual interviews) or using video conference calling such as MS Teams (for interviews and/or workshops). If Covid restrictions allow, face-to-face interviews/workshops could be conducted in Covid-secure settings e.g. well-ventilated meeting rooms in Trust/hospital buildings. Participation in interviews or workshops will be completely voluntary.

Thirdly, the researchers will review sites' self-assessment tool for the s.17 standard (developed by the research team) and practitioners' use of the tools we develop (carer information leaflet regarding s.17 leave and training slides for practitioners) to assess the extent to which they were able to implement the s.17 standard in routine practice and the timeframe for this.

Qualitative data will be analysed using thematic analysis to identify common themes focused on the feasibility and process of implementation, and the experience of the support provided. Data will be analysed iteratively to inform subsequent interviews. Any final revisions to the s.17 standard will be made at the end of the study if required.

Costs:
The cost analysis will be a simple assessment of the range of costs likely to be incurred through implementing the s.17 standard and providing enhanced support to carers, which would require formal assessment in subsequent research. Indicative costs of the s.17 standard will be calculated by compiling information on resources used (e.g.
estimates of time expended in providing the support), in addition to analysis of CSRI information to illustrate additional or reduced use of other services, with unit cost data sourced from PSSRU's annual publication.

Intervention Type
Other

Primary outcome(s)
Carers' experiences of section 17 leave measured using a custom measure designed within this study (s.17 measure) at baseline, 2 weeks after the end of the first period of s.17 leave and 6 months after baseline

Key secondary outcome(s))
1. Carers' experiences of care measured using the Zarit Burden Interview (ZBI) at baseline, 2 weeks after the end of the first period of s.17 leave and 6 months after baseline.
2. Carers' mental wellbeing measured using the Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS) at baseline, 2 weeks after the end of the first period of s.17 leave and 6 months after baseline
3. Carers' use of services measured using an adapted version of the Client Service Receipt Inventory at baseline and 6 months after baseline

Completion date
18/05/2023

Eligibility

Key inclusion criteria
Carers:
Unpaid carers (partners, friends or family members) aged 18 years or older who provide regular, ongoing assistance to a person aged 18 years or older who is currently detained under s.2 or s.3 of the Mental Health Act (1983).

Practitioners:
Practitioners, managers, and Responsible Clinicians who have been involved in the implementation of the s.17 standard in the intervention wards in the study sites and/or who have attempted to use the s.17 standard in practice. This will include staff from different inpatient wards supporting different patient groups and could include carers' leads and potentially care coordinators and crisis team staff in community teams, who have experience of working with service users and/or carers around s.17 leave.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
134

Key exclusion criteria
Exclusion criteria for this study are the inverse of the inclusion criteria. In addition:

Carers:
Carers will be excluded where it is deeemed by others (e.g. practitioners in mental health services or the local authority) that they pose a risk to others such that meetings with a mental health professional, social worker, support worker or researcher are not recommended; is currently an inpatient themselves or is currently not able to provide care; the person they provide care to has previously had s.17 leave during the current admission; or (for the second and third round of interviews) no period of s.17 leave is granted during the admission.

Practitioners:
Recruitment will not be open to practitioners, managers and Responsible Clinicians in the control wards across the study sites.

Date of first enrolment
18/02/2022

Date of final enrolment

30/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq, Willerby Hill
Beverley Road
Willerby
Hull
United Kingdom
HU10 6ED

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
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DL2 2TS

Study participating centre
Leeds and York Partnership NHS Foundation Trust
Main House
St Mary's House
St Mary's Road
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LS7 3JX

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane

Wakefield
United Kingdom
WF1 3SP

Study participating centre
North East London NHS Foundation Trust
1st Floor Maggie Lilley Suite
Goodmayes Hospital
Barley Lane
Goodmayes
United Kingdom
IG3 8XJ

Study participating centre
South West London and St George's Mental Health NHS Trust
Newton Building 7 (Entrance 11)
Springfield University Hospital
61 Glenburnie Road
London
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SW17 7DJ

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
School for Social Care Research

Alternative Name(s)
NIHR School for Social Care Research, SSCR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Martin Webber, University of York (martin.webber@york.ac.uk). Only anonymised transcripts and outcomes data will be shared openly, and only where carers and practitioners have provided consent for their anonymised data to be shared with others. Data not consented to be shared will be excluded from any datasets. The University will field any requests for access and review these on a case by case basis, making the data available to the requester when appropriate in line with the consents provided by the study participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/02/2024	10/12/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes