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Treatment of prolapse with self-care pessary: the TOPSY trial

Submission date	Recruitment status	[X] Prospectively registered
26/09/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/10/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/08/2025	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Pelvic organ prolapse (or prolapse) is a common condition in women where the pelvic organs (bladder, bowel or womb) descend into the vagina and cause distressing symptoms that adversely affect quality of life. Two thirds of women initially choose a vaginal support pessary to treat their prolapse symptoms. It is usually fitted at a gynaecological clinic and the woman returns every 6 months to have it removed and changed. However, it is possible that women could remove, clean and reinsert their pessary themselves at home (self-management), thus offering them more confidence in their ability to maintain and improve their own health. The aim of this study is to assess if self-management of prolapse using a vaginal pessary is more effective at improving women's quality of life than standard follow up care.

Who can participate?
Women aged 18 and over with any severity or kind of prolapse who have successfully used a pessary for at least 2 weeks

What does the study involve?
Women are randomly allocated to either self-management or standard care. Women in the standard care group are seen every 6 months in a hospital or community clinic for pessary removal and reinsertion. Women in the self-management group have a 30-minute appointment with a specialist nurse or physiotherapist to ensure they know how to change and clean their pessary and to allow them time to practice. Women have a follow-up phone call 2 weeks after they have received the training to discuss any issues they may have. There is a telephone number that women can call throughout the study to report any issues or concerns they have. All women complete quality of life questionnaires at the start and at 6, 12 and 18 months. Information is collected to find out if self-management is more or less expensive for the NHS and for women. To help understand how and why aspects of self-management may/ may not work some self-management sessions are recorded and some women and health professionals are interviewed.

What are the possible benefits and risks of participating?
The support systems may help to manage the participants’ pelvic organ prolapse. Taking part in the study will not benefit the participant further but the information gained may help improve the treatment of women with pelvic organ prolapse. Pessaries are widely used in the NHS as

treatment for pelvic organ prolapse. Both self-management and clinic-based care are already used within the NHS. Participation in the study is to help evaluate the support systems so no additional risks are expected. Women in the self-management group are asked to remove, clean and replace their pessary at least once every 6 months. They also receive a leaflet outlining possible complications to look out for. Some of the questions asked may seem personal but the information is important to help understand the study in full.

Where is the study run from?
Glasgow Caledonian University (UK)

When is the study starting and how long is it expected to run for?
November 2017 to January 2024

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Prof Carol Bugge, Carol.Bugge@gcu.ac.uk

Study website
https://w3.abdn.ac.uk/hsru/topsy

Contact information

Type(s)
Scientific

Contact name
Prof Carol Bugge

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 16/82/01

Study information

Scientific Title
A multi-centre randomised controlled trial , with process evaluation, to test the clinical and cost-effectiveness of self-management of vaginal pessaries to treat pelvic organ prolapse, compared to standard care to improve women's quality of life

Acronym
TOPSY

Study objectives
To determine the clinical and cost effectiveness of self-management of vaginal pessaries to treat pelvic organ prolapse, compared to standard pessary care according to the measurement of condition-specific quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/02/2018, West of Scotland Research Ethics Committee 03 (Clinical Research and Development, West Glasgow, Ambulatory Care Hospital, Dalnair Street, Glasgow, G3 8SJ, UK; Tel: +44 (0)141 232 1807; Email: WoSREC3@ggc.scot.nhs.uk), REC ref: 17/WS/0267

Study design
Multi-centre randomised controlled trial with nested process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Pelvic organ prolapse

Interventions

Current intervention as of 31/08/2022:
Women with any severity or kind of prolapse will be invited to take part in the study as long as they have successfully used a pessary for at least 2 weeks. Eligible women who provide written consent will be assigned randomly to either self-management or standard care. Women in the standard care group will be seen every 6 months in a hospital or community clinic for pessary removal and reinsertion. Women in the self-management group will have a 30 minute teaching appointment with a specialist nurse or physiotherapist trained in self-management delivery to ensure they know how to change and clean their pessary and to allow them time to practice. Women will have a follow up phone call 2 weeks after they have received the training to discuss any issues they may have. There will be a telephone number that women can call throughout the study to report any issues or concerns they have.

All women will complete quality of life questionnaires at the start and at 6, 12 and 18 months. Information will be collected to find out if self-management is more or less expensive for the NHS and for women. To help understand how and why aspects of self-management may/may not work some self-management sessions will be recorded and some women and health professionals will be interviewed.

Eligible participants who have opted in will also be sent a questionnaire at 4-year follow-up.

Previous intervention:
Women with any severity or kind of prolapse will be invited to take part in the study as long as they have successfully used a pessary for at least 2 weeks. Eligible women who provide written consent will be assigned randomly to either self-management or standard care. Women in the standard care group will be seen every 6 months in a hospital or community clinic for pessary removal and reinsertion. Women in the self-management group will have a 30 minute teaching appointment with a specialist nurse or physiotherapist trained in self-management delivery to ensure they know how to change and clean their pessary and to allow them time to practice. Women will have a follow up phone call 2 weeks after they have received the training to discuss any issues they may have. There will be a telephone number that women can call throughout the study to report any issues or concerns they have.

All women will complete quality of life questionnaires at the start and at 6, 12 and 18 months. Information will be collected to find out if self-management is more or less expensive for the NHS and for women. To help understand how and why aspects of self-management may/may not work some self-management sessions will be recorded and some women and health professionals will be interviewed.

Intervention Type

Other

Primary outcome measure

Current primary outcome measure as of 31/08/2022:
Prolapse-specific quality of life, measured using PFIQ-7 at baseline, 6, 12 and 18 months and 4 years

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Previous primary outcome measure:
Prolapse-specific quality of life, measured using PFIQ-7 at baseline, 6, 12 and 18 months

Secondary outcome measures
Current secondary outcome measures as of 31/08/2022:
1. Generic quality of life, measured using EQ-5D-5L at baseline, 6, 12 and 18 months and 4 years
2. Prolapse symptoms, measured using PFDI-21 at baseline and 18 months and 4 years
3. Sexual dysfunction, measured using PISQ-12 at baseline and 18 months and 4 years
4. Need for other prolapse treatment, measured at 6, 12 and 18 months and 4 years
5. Self-efficacy, measured using GSE/SESPPFE at baseline and 18 months and 4 years
6. Treatment acceptability, measured at at baseline and 18 months and 4 years
7. Patterns of pessary use, measured at baseline, 6, 12 and 18 months and 4 years
8. Pessary complications, measured at baseline, 6, 12 and 18 months and 4 years
9. Pessary discontinuation, measured at baseline, 6, 12 and 18 months and 4 years
10. Adherence to self-management/standard pessary care, measured continuously throughout trial
11. Crossover to other group, measured continuously throughout trial
12. Everyday physical activity assessed using the International Physical Activity Questionnaire modified for the elderly (IPAQ-E) at 4 years. The four questions ask about the amount of time in days and minutes, people spend sitting, walking, doing moderate and vigorous physical activity in the last 7 days.

Previous secondary outcome measures:
1. Generic quality of life, measured using EQ-5D-5L at baseline, 6, 12 and 18 months
2. Prolapse symptoms, measured using PFDI-21 at baseline and 18 months
3. Sexual dysfunction, measured using PISQ-12 at baseline and 18 months
4. Need for other prolapse treatment, measured at 6, 12 and 18 months
5. Self-efficacy, measured using GSE/SESPPFE at baseline and 18 months
6. Treatment acceptability, measured at at baseline and 18 months
7. Patterns of pessary use, measured at baseline, 6, 12 and 18 months
8. Pessary complications, measured at baseline, 6, 12 and 18 months
9. Pessary discontinuation, measured at baseline, 6, 12 and 18 months
10. Adherence to self-management/standard pessary care, measured continuously throughout trial
11. Crossover to other group, measured continuously throughout trial

Overall study start date
01/11/2017

Completion date
31/01/2024

Eligibility

Key inclusion criteria
1. Women with pelvic organ prolapse of any type or stage
2. Aged ≥18 years
3. Women treated with a vaginal pessary
4. Pessary retained for 2 weeks or more

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
330

Total final enrolment
340

Key exclusion criteria
1. Women with a shelf or Gellhorn pessary as these are difficult for women to remove and replace themselves
2. Women lacking in manual dexterity, e.g. those with arthritis, as women would not be able to remove and replace her own pessary
3. Women judged by the treating clinician to have a cognitive deficit such that she would be unable to give informed consent or understand self-management instruction
4. Pregnant women

Date of first enrolment
01/05/2018

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Mary's Hospital
Warrell Unit
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Glasgow Caledonian University

Sponsor details
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y.glover@gcu.ac.uk

Sponsor type
University/education

Website
http://www.gcu.ac.uk/

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The study protocol will be available on the NIHR website and the study website (https://w3.abdn.ac.uk/hsru/topsy) and will be published in an academic journal. The statistical analysis plan will be available as an appendix in the final report which will also be published on the NIHR website. Final NIHR HTA report due July 2021. Aim to publish in journals and present findings at both national and international conferences.

Intention to publish date

31/01/2025

Individual participant data (IPD) sharing plan

All data requests should be submitted to Suzanne Hagen (S.Hagen@gcu.ac.uk) for consideration. Access to anonymised data may be granted following review.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	process evaluation protocol	08/10/2020	14/10/2020	Yes	No
Protocol article	protocol	08/10/2020	14/10/2020	Yes	No
Other publications	Theoretical and practical development of the TOPSY self-management intervention for women who use a vaginal pessary for pelvic organ prolapse	05/09/2022	06/09/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		23/11/2023	19/12/2023	Yes	No
Results article	Clinical and cost-effectiveness	01/05/2024	22/05/2024	Yes	No
Results article	Long Term Follow-Up	20/08/2025	20/08/2025	Yes	No