ISRCTN87316215 https://doi.org/10.1186/ISRCTN87316215

Hypnotherapy and recovery after keyhole surgery for the gall bladder

Submission date 22/10/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/12/2010	**Overall study status** Completed	
Last Edited 16/03/2020	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
YOR-A01504

Study information

Scientific Title
Pre-operative hypnotherapy and recovery after laparoscopic cholecystectomy: a randomised controlled trial

Study objectives
Participants randomised to receive a single session of taped self-hypnosis prior to keyhole surgery to remove the gall bladder will have lower pain levels 24 hours after surgery than participants who listen to a tape of white noise prior to their surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Yorkshire and North Lincolnshire Research Ethics Committee (part of the UK 's NHS National Research Ethics Service), 31/08/2010, ref: 10/H1304/21

Primary study design
Interventional

Study design
Single-centre parallel two-group randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgical removal of the gall bladder for the treatment of cholelithiasis (gallstones) or cholecystitis (inflammation of the gall bladder)

Interventions
1. Audiotape of hypnotherapy (created and recorded by an experienced clinical hypnotherapist)
2. Audiotape of white noise (white noise produced by combining sounds of all different frequencies together. White noise is frequently used to mask other sounds especially unpleasant or unwanted sounds. Can be used therapeutically.)

Duration of intervention is an hour (listen to hypnotherapy tape or tape of white noise on one occasion prior to surgery - each tape lasts about an hour). Duration of follow up is 4 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Pain using a numeric pain scale where 0 is 'no pain' and 10 is 'worst pain imaginable'. Primary outcome is level of pain 24 hours after surgery.

Key secondary outcome(s)
1. Pain using a numeric pain scale where 0 is 'no pain' and 10 is 'worst pain imaginable'. Secondary pain outcomes measured at 4 hours, 4 days, 1 week, 2 weeks after surgery.
2. Use of pain relief medication in first two weeks after surgery
3. Blood pressure and heart rate measured on admission, at anaesthetic induction, 30 minutes into surgery, 30 minutes after regaining consciousness, 6 hours, 12 hours and 24 hours after surgery

4. Quality of life using the SF-36. Measured before surgery, day 1 after surgery, 1 week, 4 weeks and 4 months after surgery

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. Aged 18 - 90 years, either sex
2. Diagnosis of cholelithiasis and/or cholecystitis
3. Requiring elective laparoscopic cholecystectomy
4. Under the care of two named surgeons at York Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Under the age of 18 or over the age of 90 years
2. Diagnosis of cholelithiasis but requiring an open cholecystectomy
3. Requiring surgery for reasons other than cholelithiasis and/or cholecystitis
4. Requiring emergency laparoscopic cholecystectomy
5. Received hypnosis within the past 3 months
6. Current and/or past history of psychiatric illness
7. Regular use of prescribed analgesics (i.e. on repeat prescription for analgesics)
8. Severe cognitive impairment
9. Hearing impairment (the study involves listening to audio tapes)
10. Not able to understand English

Date of first enrolment
01/12/2010

Date of final enrolment
01/06/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
York Hospital
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
York Teaching Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
York Teaching Hospital NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration