

PROMETHEUS funded host trials and registration details

1. ACTWELL: A randomised control trial to assess the impact of a lifestyle intervention (ActWELL) in women invited to NHS breast screening. ISRCTN11057518 (Date registered 15/02/2017)
2. ACTIVE: External frame versus internal locking plate for articular pilon fracture fixation: a multi-centre randomised controlled trial ISRCTN98152560 (Date registered: 26/02/2018)
3. ARTISAN: Acute Rehabilitation following Traumatic anterior shoulder dISlocAtioN (ARTISAN)- A Multi Centre RCT ISRCTN63184243 (date registered 03/09/2018)
4. ASICA: Achieving Self-Directed Integrated Cancer Aftercare (ASICA) in melanoma: A randomised patient-focused trial of delivering the ASICA intervention as a means to earlier detection of recurrent and second primary melanoma. ClinicalTrials.gov Identifier: NCT03328247 (Date registered: November 1, 2017)
5. CHAMP-1: a multi-centre, cluster randomised controlled, open pilot trial to establish the feasibility of conducting a large scale study comparing an intervention discussing alcohol within routine medication consultations with usual care in community pharmacies. The CHAMP-1 pilot trial is part of a 5 year NIHR programme grant.
6. C-GALL: A randomised controlled trial comparing laparoscopic cholecystectomy with observation/conservative management for preventing recurrent symptoms and complications in adults with uncomplicated symptomatic gallstones. ISRCTN55215960 (Date registered: 27/05/2016)
7. CLEAR: A 2x2 factorial randomised open label trial to determine the clinical and cost-effectiveness of hypertonic saline (HTS 6%) and carbocisteine for airway clearance versus usual care over 52 weeks in bronchiectasis. ISRCTN89040295. Date Registered 25/06/2018
8. CPIT III: The smoking cessation in pregnancy incentives trial. ISRCTN15236311 (Date registered 13/10/2017)
9. DISC: Dupuytren's interventions surgery vs collagenase. ISRCTN18254597 (Date registered: 04/04/2017)
10. FUTURE: Female Urgency, Trial of Urodynamics as Routine Evaluation; a superiority randomised clinical trial to evaluate the effectiveness and cost effectiveness of invasive urodynamic investigations in management of women with refractory overactive bladder (OAB) symptoms. ISRCTN63268739 (Date registered: 14/09/2017)
11. GRASP: GRASP: Getting it Right: Addressing Shoulder Pain. ISRCTN16539266. Date registered 13/07/2016
12. GYY: ISRCTN13567538 (Date registered: 18/03/2019)
13. IBD BOOST: Living well with inflammatory bowel disease: optimising management of symptoms of fatigue, abdominal pain, and faecal urgency/incontinence via tailored online self-management: the IBD-BOOST programme

14. IntAct: Intraoperative Fluorescence Angiography to Prevent Anastomotic Leak in Rectal Cancer Surgery. ISRCTN13334746
15. KReBs: A Randomised Controlled Trial of the effect of a Two-layer Compression Bandage System on Knee Function following Total Knee Arthroplasty. ISRCTN87127065, date registered 20/02/2017
16. L1FE: ISRCTN16478561 (Date registered: 01/04/2019)
17. MAGIC: Melatonin for Anxiety prior to General anaesthesia In Children. ISRCTN18296119, Date registered 08/01/2019
18. MIQUIT 3: RCT and meta-analysis testing effectiveness and cost-effectiveness of a tailored text message programme (MiQuit) for smoking cessation in pregnancy. ClinicalTrials.gov Identifier: NCT03231553, date registered July 27, 2017
19. MSS3: Multiple Symptoms Study 3: pragmatic trial of a community based clinic for patients with persistent (medically unexplained) physical symptoms. Date registered, 24/09/2018
20. OTIS: Does Occupational Therapist led environmental assessment and modification reduce falls among high risk older people. ISRCTN22202133. Date registered 20/06/2016
21. PEP-TALK: A behaviour change physiotherapy intervention to increase physical activity following hip and knee replacement: a pragmatic phase III randomised controlled trial. ISRCTN29770908
22. POSNOC: Positive sentinel node: adjuvant therapy alone versus adjuvant therapy plus clearance or axillary radiotherapy. ISRCTN54765244. Date registered 25/02/2014
23. PROFHER 2: ISRCTN76296703 (Date registered: 05/04/2018)
24. PUrE RCT: ISRCTN98970319 (Date registered: 11/11/2015)
25. REFLECT: ISRCTN11992428 (Date registered 02/06/20017)
26. SARC: Salbutamol for analgesia in renal colic: A prospective, randomised, placebo-controlled Phase II trial. ISRCTN14552440. Date registered 01/07/2019
27. SSHEW: The SSHeW study - Stopping slips among healthcare workers: A research study about slip resistant footwear in the NHS workplace. Date registered ISRCTN33051393
28. SC-IL: Does Interleukin-1 Receptor Antagonist Improve Outcome following aneurysmal Subarachnoid Haemorrhage (aSAH)? A Phase III trial. ISRCTN12961797 (Date registered 04/12/2017)
29. START:REACTS: Sub-acromial spacer for Tears Affecting Rotator cuff Tendons: a Randomised, Efficient, Adaptive Clinical Trial in Surgery. ISRCTN17825590. Date registered 05/03/2018
30. SWHSI-2: ISRCTN26277546 (Date registered 15/02/2019)
31. TOPAZ: The TOPaZ Trial - Treatment of Osteogenesis Imperfecta with Parathyroid hormone and Zoledronic acid. ClinicalTrials.gov Identifier: NCT03735537. Date registered November 8, 2018
32. UK FROST: United Kingdom Frozen Shoulder Trial (UK FroST). ISRCTN48804508. Date registered 18/07/2014
33. WAX: (IRAS Project ID: 265559) (ISRCTN Registration details to be confirmed)
34. WORKWELL: A randomised controlled trial of job retention vocational rehabilitation for employed people with inflammatory arthritis: the WORKWELL trial. ISRCTN61762297, Date registered 13/05/2019

Characteristics of currently funded host randomised controlled trials

T r i a l	Aim	Speciality	Condition	Study design	Date of recruitment	Setting	Population	Intervention (s)	Comparator	No. of expected participants	Follow up time points and modality	Primary outcome	Overall trial end date
A C T I V E	Assess the effectiveness of external fixation versus internal fixation for Type C pilon fractures	Trauma and Orthopaedics	Treatment of ankle fractures	2 arm RCT	9/3/2018 to 28/2/2021	Multicentre, Secondary care, UK	Adults with Pilon C fracture	internal fixation	external fixation	334	3, 6, 12 and 24 months by postal questionnaire	Disability Rating Index (DRI) at 12 months post-randomisation	31/08/2022
A C T W E L L	Assess the impact of a lifestyle intervention in women invited to NHS breast screening	Not Applicable (NA)	Obesity	2 arm RCT	01/07/2017 to 14/08/2018	Multicentre, UK	Women aged 50-70 years, BMI >25 km/m ²	Lifestyle intervention	Usual care	552	3 months by telephone 12 months by research nurses	Change in body weight and change in physical activity at 12 months	unclear
A R T I S A N	Assess if a course of physiotherapy is of clear benefit when compared to a single session of advice	Trauma and orthopaedics	Traumatic anterior shoulder dislocation	2 arm RCT	01/11/2018 to 30/09/2020	Multicentre, secondary care, UK	Adults with traumatic shoulder dislocation	A course of physiotherapy	A single advice session	478	6 weeks, 3, 6 and 12 months by postal questionnaire	Oxford Shoulder Instability Score at 6 months	30/11/2021
A S I C A	Compare a self-directed digital intervention with treatment as usual in patients treated for a first-stage 0-2C primary cutaneous melanoma	Dermatology	Diagnosis of melanoma recurrence	2 arm RCT	01/01/2018 to 01/03/2019	Multicentre, Secondary care, UK	Adults >18 with melanoma	ASICA digital app	Usual care	240	3, 6 and 12 months by postal questionnaire	the Melanoma Worry Scale, HADS and EQ-5D-5 L at 12 months	01/03/2020
C H A M P - 1	Incorporating discussion of alcohol within medication consultations in community pharmacy	NA	Alcohol misuse	2 arm RCT	24/06/2019 to 07/08/2019	Multicentre, UK	Adults screened positive for unhealthy drinking on a single item alcohol screening question	Incorporate discussion of alcohol	Usual medication consultation	820	2 months by telephone	Alcohol consumption at 2 months	31/12/2022

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C - G A L L	To find out whether there any differences between conservative management and cholecystectomy in terms of patient quality of life and cost-effectiveness	Surgery	Gallstones	2-arm RCT	01/09/2016 to 01/08/2018	Multicentre, Secondary care, UK	Adults aged over 18 with symptomatic uncomplicated gallstone disease	Medical management with analgesia, as required, and dietary advice	Laparoscopic cholecystectomy	430	3, 9 and 18 months questionnaire	Quality of life using area under the curve (AUC) at up to 18 months post-randomisation using the SF-36 bodily pain domain	01/10/2020
C L E A R	Assess the effectiveness of hypertonic saline and carbocysteine combinations in airway clearance	Respiratory	Bronchiectasis	2x2 factorial RCT	27/06/2018 to 31/12/2020	Multicentre, secondary care, UK	Adults with bronchiectasis	Saline, carbocysteine	Usual Care	Unclear	2, 8, 26, 52 weeks questionnaire at visits	Mean number of exacerbations over 52 weeks	30/06/2022
C P I T I I	Assess the effectiveness of financial incentive to encourage pregnant smokers engaging with smoking cessation service and quite smoking	Obstetrics	Smoking cessation	2 arm RCT	01/02/2018 to 31/12/2019	Multicentre, Secondary care, UK	Pregnant women (less than 24 weeks) aged >16	Up to £400 depending on engagement with smoking cessation services and negative CO testing at 3 time-points	Offer of smoking cessation and up to £75 on completion of trial follow-up	940	34-38 weeks gestation and 6 month post-partum for every participant by postal questionnaire, intervention group will be followed up face-to-face at smoking cessation services (SCS) + 4 and 12 weeks post SCS	Self-reported abstinence for at least 8 weeks prior to 34-38 weeks gestation	30/11/2020
D I S C	Assess the effectiveness of collagenase injections in Dupuytren's Contractures (DC)	Plastic Surgery	Treatment of DC	2 arm RCT	01/05/2017 to 31/10/2019	Multicentre, Secondary care, UK	Adults >18 with DC	Collagenase injections	limited fasciectomy surgery	710	3, 6, 12 and 24 months at clinics	Patient Evaluation Measure at baseline, 3, 6, 12 and 24 months	31/10/2021

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F U T U R E	Whether routine Urodynamics investigation and comprehensive clinical assessment significantly improves patient-reported success rates following treatment, compared to comprehensive clinical assessment only	Reproductive Health and Childbirth	Overactive bladder (OAB)	2 arm RCT	01/10/2017 to 31/05/2020	Multicentre, Secondary care, UK	Women ≥ 18 years of age	comprehensive clinical assessment only	Urodynamics plus comprehensive clinical assessment	1096	3, 6, and 15 months by postal questionnaire	Patient Global Impression of Improvement - Index (PGI-I)	30/04/2022
G R A S P	Assess cost effectiveness of progressive exercise in rotator cuff disorders	Musculoskeletal	Rotator cuff disorders	2x2 factorial RCT	01/02/2017 to 02/05/2019	Multicentre, secondary care, UK	Adults >18 with rotator cuff disorder	Progressive exercise programme, best practice advice session, injection	best practice advice session	704	2, 6 and 12 month by postal questionnaires	Shoulder pain and disability index	31/08/2021
G Y Y	Assess the effectiveness of a yoga programme in older adults with multi-morbidity	Chronic illness	Treatment of multi-morbidity	2 arm RCT	01/07/2019 to 01/07/2021	Multicentre, Primary care, UK	Adults aged >65 with 2 or more chronic health conditions	12-week British Wheel of Yoga Gentle Years Yoga	Usual care	586	3, 6, 12 months by postal questionnaires	EQ-5D-5L utility score at 12 months	31/12/2022
I B D B O O S T	Improve quality of life of people with Inflammatory bowel disease (IBD) by reducing symptoms	Gastroenterology	IBD	RCT	Unclear?	Secondary care, UK	Patients with IBD	Online training package for nurses, and online self-management programme	Usual care	680	Unclear?	Condition specific quality of life at 6 months	10/2022
I n t A c t	evaluate whether intraoperative fluorescent angiography (IFA) is able to decrease anastomotic leak (AL) rate	Colorectal surgery	Rectal cancer	2 arm RCT	01/07/2017 to 31/08/2020	Secondary care	Adults >18 with rectal cancer undergoing curative elective surgery	IFA with surgery	Surgery only	880	30 and 90 days by questionnaire and clinical examination	Clinical anastomotic leak rate at 90 days	31/05/2021

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K R e B s	effect of a Two-layer Compression Bandage System on Knee Function following Total Knee Arthroplasty	Orthopaedics	Total knee replacement	2 arm RCT	01/03/2017 to 31/08/2018	Multicentre, secondary care, UK	Adults having a total knee replacement	2 layer compression bandage	Crepe bandage and synthetic wool layer	2600	10 days, 4 weeks, 6 and 12 month postal questionnaire	Oxford knee score 12 months postoperatively	30/04/2020
L 1 F E	Assess the effectiveness of surgical fixation with INFIX compared to non-surgical management of LC-1 fragility fractures in older adults	Trauma and Orthopaedics	Treatment of Pelvic fractures	2 arm RCT	09/07/2018 to 31/07/2019	Multicentre, Secondary care, UK	Adults >60 with a LC-1 fracture with severe pain and reduced mobility	Surgical fixation	Non operative management	600	2 weeks by postal questionnaires or telephone interview. 4 weeks, 12 weeks and 6 months follow up in clinic	EQ-5D-5L at 6 months	31/03/2023
M A G I C	Assess the effectiveness of Melatonin as pre-medication for surgery in children	Surgery	Dental ophthalmological or ENT surgery	2 arm RCT	10/07/2019 to 15/07/2020	Multicentre, secondary care, UK	Children aged 5-14 years undergoing dental/ophthalmological/ENT surgery	Melatonin	Midazolam	1650	14 days telephone follow-up	Preoperative distress using the modified Yale Preoperative Anxiety Scale	15/07/2021
M I Q U I T 3	Determine whether or not MiQuit (text-message support programme) is effective in addition to standard support for smoking cessation in pregnancy	Obstetrics	Smoking cessation	2 arm RCT	unclear	Multicentre, UK	Pregnant women <25 weeks gestation, aged 16 or over	Receive MiQuit text message cessation programme	Usual care	692	Up to 36 weeks gestation, via text messaging	Self-reported smoking abstinence	01/01/2020
M S S 3	Determine whether a 50-minute symptoms clinic is cost effective for medically unexplained symptoms (MUS)	General Practice	MUS	2 arm RCT	15/10/2018 to 31/10/2019	Multicentre, Primary care, UK	Adults aged between 18-69 with MUS	50-minute symptoms clinic with 15 minute follow-ups	Usual care	376	12 and 52 weeks postal questionnaire	PHQ-15 at 52 weeks	31/07/2021
O T I S	Assess the effectiveness of an occupational therapist led home environmental assessment and modification for high risk of falling in older people	General Practice	Falls	2 arm RCT	01/18/2016 to 02/08/2018	Multicentre, Primary care, UK	Older people aged 65 and older with risk factors for falls	an occupational therapist led home environmental assessment and a falls prevention leaflet	Usual care	1299	4, 8 and 12 months postal questionnaire	Number of falls experienced in the 12 months	31/12/2019

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P E P - T A L K	Assessing the effectiveness of group discussion in addition to physiotherapy on improving physical activity following hip and knee replacement.	Musculoskeletal diseases	Hip and knee replacement	2 arm RCT	01/01/2019 to 31/12/2019	Multicentre, secondary care, UK	Adults following primary unilateral total hip or knee replacement	Group based exercise sessions in addition to physiotherapy	Physiotherapy only	250	6 and 12 months questionnaire (postal or online)	Physical activity at 6 and 12 months (using the UCLA activity scale)	31/07/2021
P O S S I B L E	Assess the effectiveness of adjuvant therapy alone versus adjuvant therapy plus clearance or axillary radiotherapy in women with early stage breast cancer.	Cancer	Breast cancer	2 arm RCT	01/01/2014 to 31/08/2021	Multicentre, secondary care, international	Women >18 years with early breast cancer, with macro-metastasis in sentinel node biopsy.	Adjuvant therapy alone	Adjuvant therapy plus axillary treatment (usual care)	1900	3, 6, 12, 24 and 36 months	Axillary recurrence at 5 years	31/12/2023
P R O F H E R 2	Assess the effectiveness of reverse shoulder arthroplasty, hemiarthroplasty and non-surgical treatment for proximal humerus fractures	Trauma and Orthopaedics	Treatment of proximal humeral fractures	3 arm RCT	01/06/2018 to 31/05/2021	Multicentre, Secondary care, UK	Adults >65 with a 3-4 part humeral fracture	Reverse Shoulder Arthroplasty vs hemi-arthroplasty	Conservative management	380	6 months face-to-face follow-up. Postal questionnaire at 1 year and 2 years	Oxford Shoulder Score at 6, 12 and 24 months	31/05/2023
P U R E R C T	Assess the effectiveness of three treatment options for lower kidney stones	Urology	Treatment of urolithiasis	2 arm RCT	01/05/2015 to 02/06/2019	Multicentre, Secondary care, UK	Adults >16 with lower pole stones	FURS	Usual care (PCNL or ESWL)	1044	Weekly up to 12 weeks, 3 months and 12 months by questionnaires either face-to-face, postal, phone or email	EQ-5D-5L at 1, 2, 4, 8, and 12 weeks	01/12/2020

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R E F L E C T	To evaluate the effectiveness and cost benefit of General Dental Practitioner (GDP) prescribing of 5000 ppm fluoride toothpaste and usual care compared to usual care alone in individuals 50 years and over with high-risk of caries	Dentistry	Dental Caries	2 arm RCT	10/02/2018 to 30/09/2019	Multicentre, General dental practices, UK	Adults aged 50 and over	Prescription of 5000ppm fluoride toothpaste by dentist	Usual care	1174	12, 24 and 36 months by patient questionnaire; clinical assessments up to 36 months	Number and proportion of individuals requiring restoration or extraction or endodontic treatment due to caries	30/06/2022
S A R C	Does salbutamol reduce the pain of kidney stones when used alongside normal pain relief?	Urological and genital diseases	Kidney stones	2 arm RCT	16/09/2019 to 01/08/2021	Secondary care, UK	Adults with a working diagnosis of renal colic	Salbutamol	placebo	118	15, 30, 60 and 120 minutes questionnaire during visit	Change in pain score measured using visual analogue scale at 30 minutes	31/12/2021
S S H E W	Whether wearing slip resistant shoes can reduce the number of slips, falls and injuries NHS staff have at work.	Signs and symptoms	Slips, falls and injuries	2 arm RCT	10/03/2017 to 10/01/2019	Multicentre, secondary care, UK	NHS staff	Slip resistant shoes	Usual work footwear	4400	14 weekly text messages	Self-reported slips in the workplace	10/01/2019
S C I L	Does Interleukin 1 Receptor Antagonist Improve Outcome following Aneurysmal Subarachnoid Haemorrhage	Aneurysmal Subarachnoid Haemorrhage	Stroke	3 arm RCT	31/05/2018 to 30/11/2021	Multicentre, Secondary care, UK	Adults aged 18 and older with Subarachnoid haemorrhage (SAH)	Subcutaneous injections of IL-1Ra twice daily for up to 21 days	Placebo twice daily for 21 days	1000	Clinical data at 3-5 days and 30 days post randomisation, and at 6 months	Modified Rankin Scale (mRS) questionnaire at 6 month	31/10/2022
S T A R T : R E A C T S	Compare arthroscopic debridement (the standard treatment) to arthroscopic debridement with the InSpace balloon on shoulder function, pain and quality of life following shoulder surgery for rotator cuff tears that cannot be repaired.	Musculoskeletal diseases	Rotator cuff tears	2 arm RCT	01/06/2018 to 30/06/2020	Multicentre, secondary care UK	Patients with irreparable rotator cuff tear	Arthroscopic debridement with the InSpace balloon	Usual care	212	3, 6 and 12 month questionnaire	Shoulder function measured with Constant-Murley score at 12 months	31/12/2021

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T O P A Z	Assess the effectiveness of parathyroid hormone and zoledronic acid treatment of osteogenesis imperfecta	Orthopaedics	Osteogenesis imperfecta	2 arm RCT	Unclear?	Multicentre, secondary care, UK	Adults with osteogenesis imperfecta	Teriparatide and zoledronic acid	Usual care (bisphosphonate treatment)	380	12 and 24 months visits, telephone calls every 6 months	Incidental fractures (validated by xray or other imaging) (approx. 5 years)	01/04/2023
U K F R O S T	Assess effectiveness of early structured physiotherapy (ESP) versus manipulation under anaesthesia (MUA) versus arthroscopic capsular release (ACR)	Musculoskeletal disease	Frozen shoulder	3 arm RCT	01/01/2015 to 31/12/2017	Multicentre, secondary care, UK	Adults with frozen shoulder	MUA or ACR with MUA	ESP	503	3, 6 and 12 months questionnaires	Oxford shoulder score at 12 months	30/06/2019
S W H S I - 2	Assess the effectiveness of Negative Pressure Wound Therapy (NPWT) on wound healing	General Surgery	Treatment of surgical wounds	2 arm RCT	01/05/2019 to 30/04/2021	Multicentre, Secondary care, UK	Adults >16 with an open surgical wound	NPWT	Usual care	696	weekly phone follow-up until wound healing, 3 face to face visits after wound healing, postal questionnaires at 3,6 and 12 months	Time to healing in days from randomisation	30/04/2022
W A X	In younger adults with unstable ankle fractures treated with close contact casting, is ankle function not worse than those treated with surgical intervention?	Ankle Surgery	Management of ankle fractures	2 arm non-inferiority RCT	In set-up	Multicentre, Secondary care, UK	Adults 18-60 years	close contact cast	Surgery	436	8 weeks, 4 months, 12 months, up to 5 years	Olerud and Molander ankle score (OMAS) at 4 months post randomisation	31/06/2022
W O R K W E L L	Assessing the effectiveness of work advice for people with arthritis	Musculoskeletal diseases	Inflammatory arthritis	2 arm RCT	18/02/2019 to 30/06/2020	Multicentre, UK	Adults with inflammatory arthritis	Face to face contact with a WORKWELL therapist (identifying work problems and providing advice)	Self-help information pack	240	6 and 12 month questionnaire	Presenteeism (work productivity) measured using Combined Work Activities Limitations Scale at 12 months	31/01/2022