



The Sunflower Study

Welcome to the
5th Sunflower Study
Investigator's Meeting

18th May 2023

Twitter: @sunflowerstudy
#SunflowerStudyMeeting2023



The Sunflower study is funded by the NIHR HTA Programme (project number 16/142/04). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR HTA or the Department of Health.



Study Background

Study Population:

- Adults at low or moderate risk of CBD stones who are fit and scheduled to undergo LC

Primary Outcome:

- Any hospital admission within 18 months of randomisation for treatment of a complication of gallstones (CBD or gallbladder)
- Complications during admission for LC for the treatment of gallstones or any readmission for complications of the LC leading to a hospital stay of >2 days
- Complications during any ERCP for the treatment for gallstones

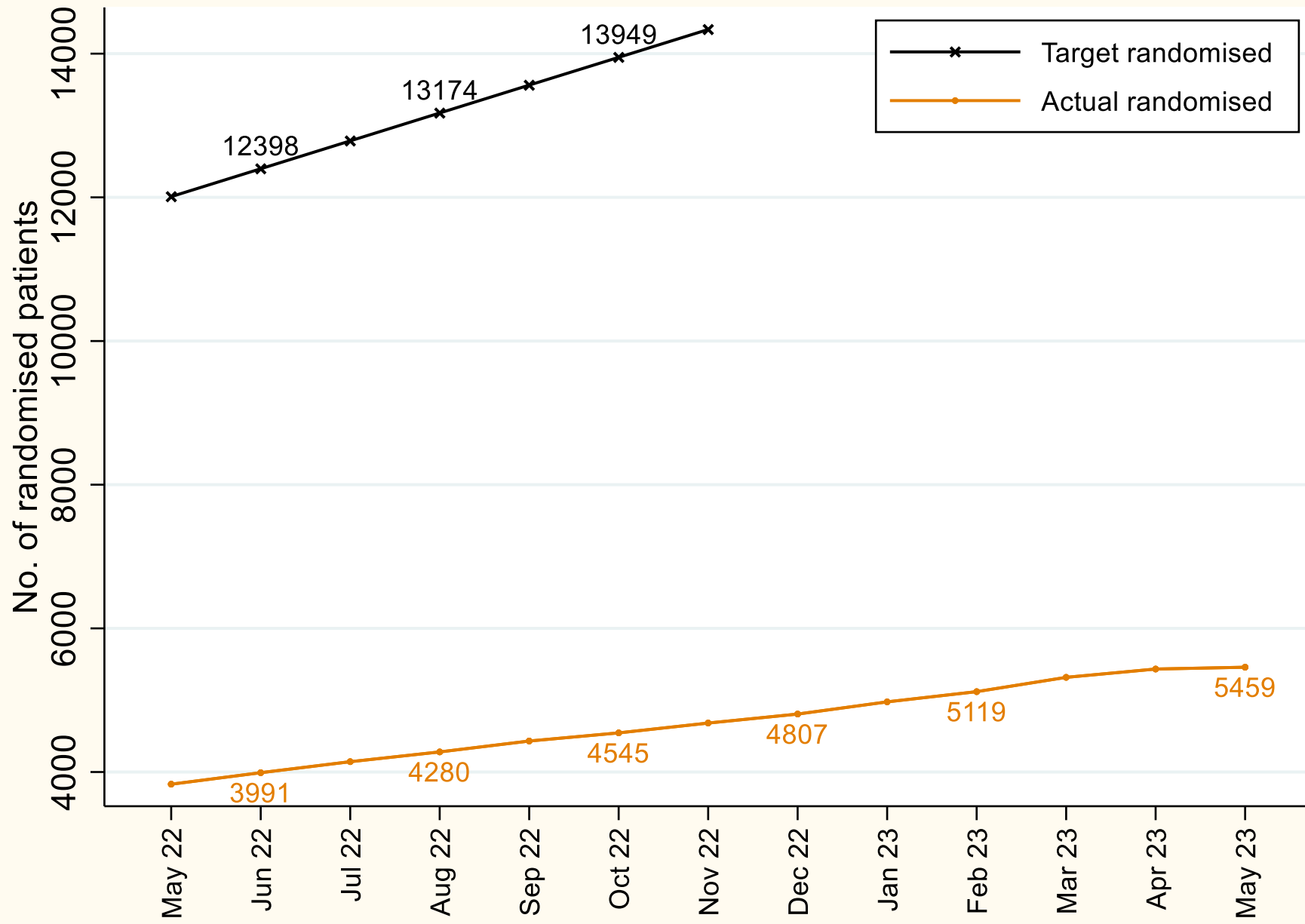
Study milestones

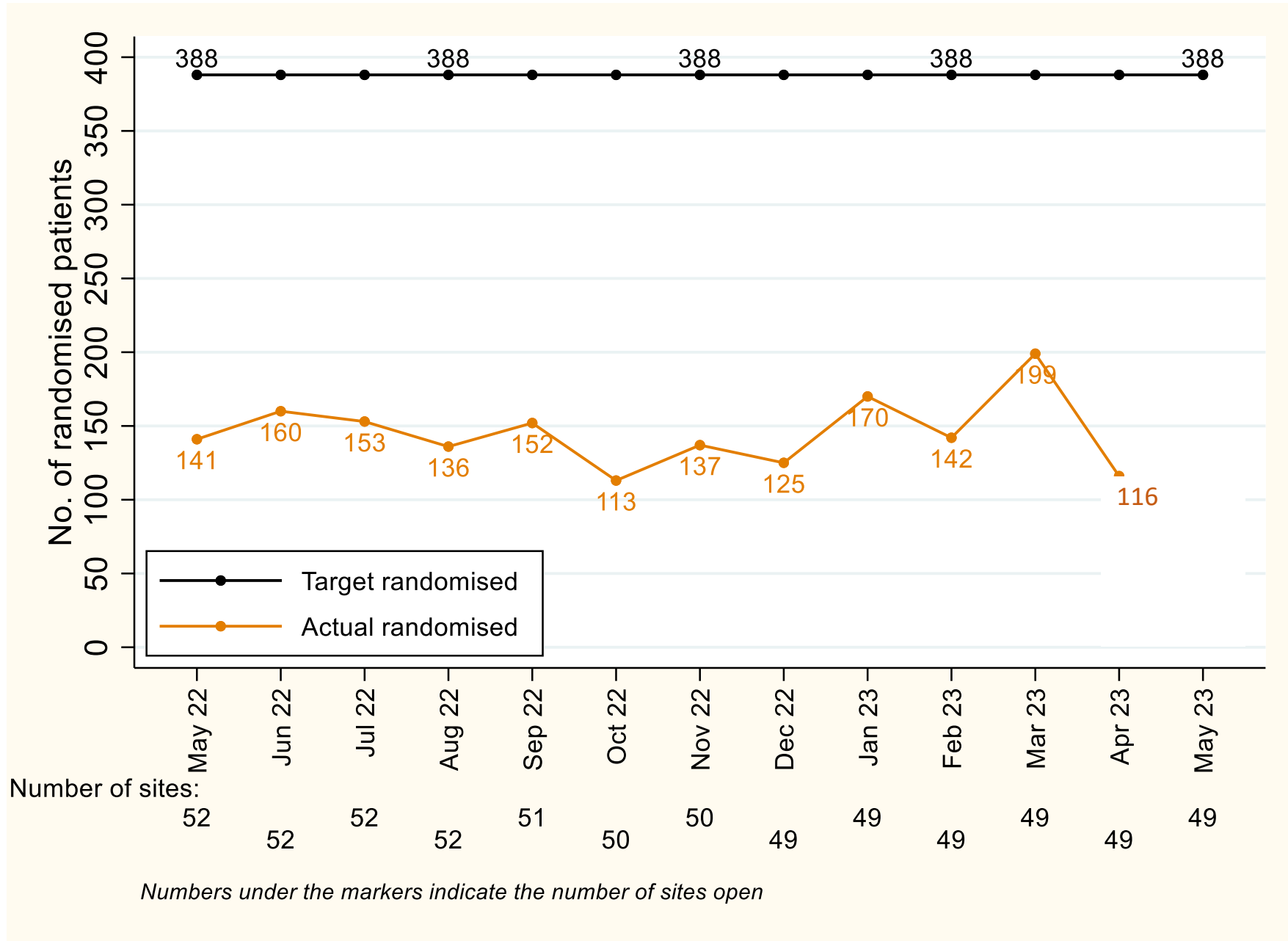
July 2018	1 st Full investigators' meeting
Jan 2019	First patient randomised (Calderdale & Huddersfield)
June 2019	2 nd full investigators meeting
July 2019	500 th patient randomised
October 2019	1000 th patient randomised (Worcester)
Jan 2020	First Associate PI received their certificate
March 2020	Recruitment pause
July 2020	Go ahead to progress to phase 2

November 2020	Virtual investigators' meetings
December 2020	50 th site opened (Northampton General)
May 2021	2500 th patient randomised
June 2021	Protocol paper published
October 2021	First radiology APIs
Feb 2022	100 th API registered via Sunflower
July 2022	4000 th patient randomised (Durham & Darlington)
October 2022	Approval from funder to continue
November 2022	Trainee Executive Group appointed
Feb 2023	5000 th patient randomised (York & Scarborough)
April 2023	Nottingham randomise 51 patients in a month!
May 2023	5 th Investigators meeting

In 4 years of recruitment....

- ☀️ **12081** patients have been screened for Sunflower
- ☀️ **9392** of these were deemed eligible
- ☀️ **7536** of the eligible patients were approached
- ☀️ **5459** have been randomised





Centres recruiting last 12 months	Recruitment (n)	Elective*	Urgent*
Nottingham	176	169 (96%)	7 (4%)
Leeds	141	23 (16%)	117 (84%)
Worcester	111	58 (53%)	51 (47%)
Gloucester	92	63 (71%)	26 (29%)
Musgrove Park	73	57 (78%)	16 (22%)
Stockton	70	62 (97%)	2 (3%)
Chester	58	45 (78%)	13 (22%)
Northern Devon	56	50 (89%)	6 (11%)
Forth Valley	56	35 (63%)	21 (38%)
County Durham and Darlington	55	39 (71%)	16 (29%)
William Harvey	52	27 (52%)	25 (48%)
Belfast	46	1 (2%)	45 (98%)
Milton Keynes	43	43 (100%)	0 (0%)
Royal Bolton	40	39 (100%)	0 (0%)
Derby	39	34 (87%)	5 (13%)
Northumbria	38	36 (97%)	1 (3%)
York and Scarborough	36	22 (61%)	14 (39%)
Northampton General	34	17 (50%)	17 (50%)
Southend	27	27 (100%)	0 (0%)
Worthing	27	16 (59%)	11 (41%)

* Admission type pending in some cases