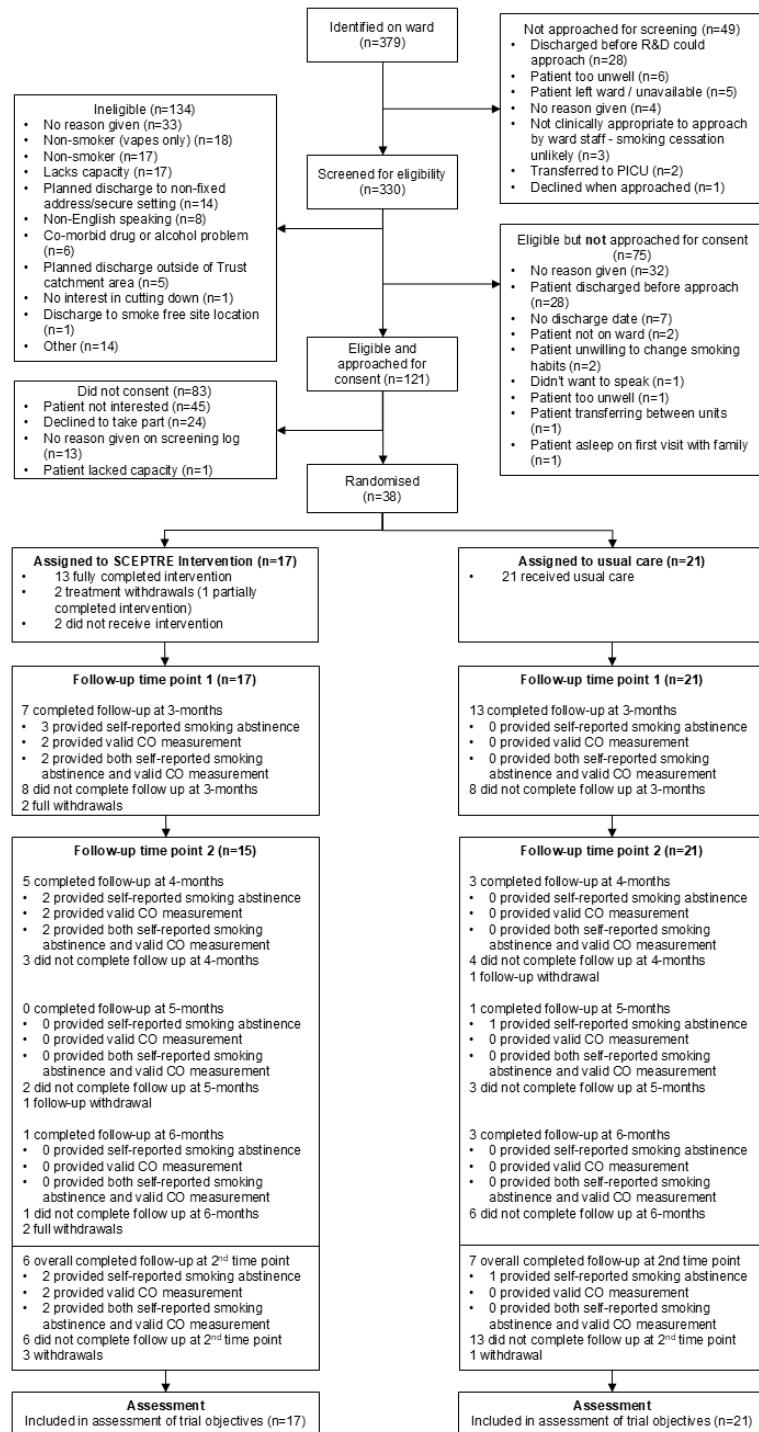


SCEPTRE Feasibility Analysis

1 Trial Progression

Figure 1: CONSORT Diagram



2 Screening

Table 1: Reasons for not approaching to begin screening.

Reason for not screening	N=49
Discharged before R&D could approach	28 (57.1)
Patient too unwell	6 (12.2)
Patient left ward / unavailable	5 (10.2)
No reason given	4 (8.2)
Not clinically appropriate to approach by ward staff - smoking cessation unlikely	3 (6.1)
Transferred to PICU	2 (4.1)
Declined when approached	1 (2.0)

Table 2: Reasons for ineligibility.

Reason for ineligibility	N=134
No reason given on screening log	33 (24.6)
Non-smoker (vapes only)	18 (13.4)
Non-smoker	17 (12.7)
Lack capacity	17 (12.7)
Planned discharge to non-fixed address/secure setting	14 (10.4)
Non-English speaking	8 (6.0)
Co-morbid drug or alcohol problems	6 (4.5)
Planned discharge outside of Trust catchment area	5 (3.7)
Discharge to a smoke free site location	1 (0.7)
No interest in cutting down	1 (0.7)
Other	14 (10.4)

Table 3: Reasons for not approaching patient for consent

Reason for non-approach	N=75
No reason given	32 (42.7)
Discharged quickly / Unaware of discharge	28 (37.3)
No discharge plan / awaiting discharge date	7 (9.3)
Unwilling to change smoking habits	2 (2.7)
Patient not on ward	2 (2.7)
Approached but didn't want to speak. Staff discussed; smoking cessation unlikely, not appropriate to approach again	1 (1.3)
Currently transferring between units	1 (1.3)
Patient asleep on first visit with family	1 (1.3)
Patient too unwell	1 (1.3)

Table 4: Reasons for not participating in the study

Reason for non-consent	N=83
Patient not interested	45 (54.2)
Declined to take part	24 (28.9)
No reason given	13 (15.7)
Patient lacked capacity	1 (1.2)

3 Baseline demographics and PROMs

Table 5: Participant baseline characteristics summarised by randomised group and overall.

	SCEPTRE intervention	Usual Care	Overall
	N=17	N=21	N=38
Age (Years)			
N (% data available)	17 (100.0)	21 (100.0)	38 (100.0)
Mean (SD)	38.2 (9.7)	35.2 (10.4)	36.6 (10.1)
Median	40	32	36
Min, Max	21, 56	19, 59	19, 59
Gender, N (%)			
Male	7 (41.2)	13 (61.9)	20 (52.6)
Female	9 (52.9)	8 (38.1)	17 (44.7)
Non-binary	1 (5.9)	0 (0.0)	1 (2.6)
Ethnicity, N (%)			
White (any White background)	15 (88.2)	14 (66.7)	29 (76.3)
Mixed / Multiple ethnic groups	1 (5.9)	0 (0.0)	1 (2.6)
Asian / British Asian	1 (5.9)	2 (9.5)	3 (7.9)
Black / African / Caribbean / Black British	0 (0.0)	4 (19.0)	4 (10.5)
Other: Please specify	0 (0.0)	1 (4.8)	1 (2.6)
Highest educational qualification, N (%)			
GCSE / O-level / CSE	5 (29.4)	9 (42.9)	14 (36.8)
A-level or equivalent	6 (35.3)	6 (28.6)	12 (31.6)
Bachelor's degree or equivalent	3 (17.6)	1 (4.8)	4 (10.5)
Masters/PhD or equivalent	0 (0.0)	1 (4.8)	1 (2.6)
No formal qualifications	1 (5.9)	4 (19.0)	5 (13.2)
Other: Please specify	2 (11.8)	0 (0.0)	2 (5.3)
Employment status, N (%)			
Working: Full-time (30+ hours per week)	4 (23.5)	2 (9.5)	6 (15.8)
Working: Part-time (< 30 hours per week)	0 (0.0)	1 (4.8)	1 (2.6)
Working: Self-employed	1 (5.9)	1 (4.8)	2 (5.3)
Not working: Looking for work.	0 (0.0)	2 (9.5)	2 (5.3)
Not working: Illness/disability.	12 (70.6)	11 (52.4)	23 (60.5)
Other: Please specify	0 (0.0)	4 (19.0)	4 (10.5)
Current accommodation type, N (%)			
Owned/mortgaged	1 (5.9)	0 (0.0)	1 (2.6)
Rented: Private Tenant	5 (29.4)	1 (4.8)	6 (15.8)
Rented: Social housing provider	5 (29.4)	10 (47.6)	15 (39.5)
Supported accommodation	3 (17.6)	1 (4.8)	4 (10.5)
Living with family members	1 (5.9)	7 (33.3)	8 (21.1)
Living with friends	0 (0.0)	1 (4.8)	1 (2.6)
Other: Please specify	1 (5.9)	1 (4.8)	2 (5.3)
Missing	1 (5.9)	0 (0.0)	1 (2.6)
Marital status, N (%)			
Single	14 (82.4)	15 (71.4)	29 (76.3)
Married / Civil Partner	0 (0.0)	3 (14.3)	3 (7.9)
Living with a partner / co-habiting	1 (5.9)	1 (4.8)	2 (5.3)
Divorced/separated	2 (11.8)	2 (9.5)	4 (10.5)

Table 6: Participant admission and discharge data summarised by randomised group and overall.

	SCEPTRE intervention	Usual Care	Overall
	N=17	N=21	N=38
Time on ward (days)			
N (% data available)	17 (100.0)	20 (95.2)	37 (97.4)
Mean (SD)	70.1 (62.7)	54.1 (41.9)	61.4 (52.4)
Median	49	43	45
Min, Max	23, 279	20, 211	20, 279
Type of admission, N (%)			
Voluntary	10 (58.8)	8 (38.1)	18 (47.4)
Compulsory	7 (41.2)	13 (61.9)	20 (52.6)
Number of diagnoses, N (%)			
0	1 (5.9)	0 (0.0)	1 (2.6)
1	14 (82.4)	18 (85.7)	32 (84.2)
2	1 (5.9)	2 (9.5)	3 (7.9)
3	1 (5.9)	1 (4.8)	2 (5.3)
Diagnosis (Not mutually exclusive), N (%)			
Schizophrenia or other primary psychotic disorders	7 (41.2)	13 (61.9)	20 (52.6)
Personality disorders and related traits	8 (47.1)	4 (19.0)	12 (31.6)
Mood disorders	2 (11.8)	4 (19.0)	6 (15.8)
Mental or behavioural symptoms, signs or clinical findings	0 (0.0)	1 (4.8)	1 (2.6)
Disorders due to substance use or addictive behaviours	0 (0.0)	2 (9.5)	2 (5.3)
Neurodevelopmental disorders	1 (5.9)	0 (0.0)	1 (2.6)

Table 7: Baseline PROMs summarised descriptively overall and by treatment group.

	SCEPTRE intervention	Usual Care	Overall
	N=17	N=21	N=38
7-day point prevalence			
Self-reported as abstinent, N (%)			
No	16 (94.1)	17 (81.0)	33 (86.8)
Yes	1 (5.9)	4 (19.0)	5 (13.2)
CO-validated as abstinent, N (%)			
No	16 (94.1)	17 (81.0)	33 (86.8)
Yes	1 (5.9)	4 (19.0)	5 (13.2)
Continuous abstinence			
Length of time since last smoked, N (%)			
0-7 days ago	16 (94.1)	17 (81.0)	33 (86.8)
2-3 weeks ago	1 (5.9)	2 (9.5)	3 (7.9)
1-2 months ago	0 (0.0)	2 (9.5)	2 (5.3)
CO measurement			
CO reading collected, N (%)			
No	1 (5.9)	1 (4.8)	2 (5.3)
Yes	16 (94.1)	20 (95.2)	36 (94.7)
CO reading, N (%)			
0-4 ppm	8 (47.1)	10 (47.6)	18 (47.4)

5-9 ppm	1 (5.9)	3 (14.3)	4 (10.5)
>=10 ppm	7 (41.2)	7 (33.3)	14 (36.8)
Missing	1 (5.9)	1 (4.8)	2 (5.3)
HSI			
Time until first cigarette after waking up, N (%)			
Within 5 minutes	3 (17.6)	3 (14.3)	6 (15.8)
6-30 minutes	2 (11.8)	3 (14.3)	5 (13.2)
31-60 minutes	3 (17.6)	4 (19.0)	7 (18.4)
After 60 minutes	8 (47.1)	9 (42.9)	17 (44.7)
Missing	0 (0.0)	1 (4.8)	1 (2.6)
Not applicable	1 (5.9)	1 (4.8)	2 (5.3)
Cigarettes typically smoked each day, N (%)			
10 or fewer	10 (58.8)	16 (76.2)	26 (68.4)
11-20 cigarettes	4 (23.5)	3 (14.3)	7 (18.4)
21-30 cigarettes	1 (5.9)	0 (0.0)	1 (2.6)
31 or more	1 (5.9)	1 (4.8)	2 (5.3)
Not applicable	1 (5.9)	1 (4.8)	2 (5.3)
HSI Overall Score			
N (% data available)	16 (94.1)	19 (90.5)	35 (92.1)
Mean (SD)	1.6 (2.0)	1.3 (1.6)	1.4 (1.8)
Median	1	1	1
Min, Max	0, 6	0, 6	0, 6
Strength of urges to smoke			
Frequency of urges to smoke in the past 24hrs, N (%)			
Not at all	1 (5.9)	3 (14.3)	4 (10.5)
A little of the time	4 (23.5)	7 (33.3)	11 (28.9)
Some of the time	4 (23.5)	4 (19.0)	8 (21.1)
A lot of the time	6 (35.3)	4 (19.0)	10 (26.3)
Almost all of the time	0 (0.0)	1 (4.8)	1 (2.6)
All of the time	2 (11.8)	2 (9.5)	4 (10.5)
Strength of urges in general, N (%)			
Light	2 (11.8)	4 (19.0)	6 (15.8)
Moderate	9 (52.9)	10 (47.6)	19 (50.0)
Strong	2 (11.8)	3 (14.3)	5 (13.2)
Very strong	2 (11.8)	3 (14.3)	5 (13.2)
Extremely strong	2 (11.8)	1 (4.8)	3 (7.9)
Strength of urges to smoke overall Score			
N (% data available)	17 (100.0)	21 (100.0)	38 (100.0)
Mean (SD)	6.9 (2.2)	6.3 (2.5)	6.6 (2.4)
Median	7	6	6
Min, Max	3, 12	3, 12	3, 12
Motivation to stop smoking			
Importance, N (%)			
Not at all important	0 (0.0)	4 (19.0)	4 (10.5)
Quite important	8 (47.1)	3 (14.3)	11 (28.9)
Very important	7 (41.2)	12 (57.1)	19 (50.0)
Desperately important	2 (11.8)	2 (9.5)	4 (10.5)
Determination, N (%)			
Not all that determined	1 (5.9)	3 (14.3)	4 (10.5)
Quite determined	11 (64.7)	6 (28.6)	17 (44.7)
Very determined	3 (17.6)	8 (38.1)	11 (28.9)

Extremely determined	2 (11.8)	4 (19.0)	6 (15.8)
Chance, N (%)			
Very low	1 (5.9)	2 (9.5)	3 (7.9)
Low	1 (5.9)	2 (9.5)	3 (7.9)
Not very high	4 (23.5)	1 (4.8)	5 (13.2)
Quite high	5 (29.4)	10 (47.6)	15 (39.5)
Very high	5 (29.4)	6 (28.6)	11 (28.9)
Extremely high	1 (5.9)	0 (0.0)	1 (2.6)
Motivation to stop smoking overall Score			
N (% data available)	17 (100.0)	21 (100.0)	38 (100.0)
Mean (SD)	8.9 (2.1)	9.0 (2.4)	8.9 (2.2)
Median	8	9	9
Min, Max	6, 13	3, 13	3, 13
Reasons for motivation, N (%)			
Because my health is already suffering	3 (17.6)	4 (19.0)	7 (18.4)
Because I am worried about my future health	4 (23.5)	6 (28.6)	10 (26.3)
Because smoking costs too much	4 (23.5)	3 (14.3)	7 (18.4)
For my family's health	3 (17.6)	3 (14.3)	6 (15.8)
Other (please specify):	3 (17.6)	5 (23.8)	8 (21.1)
E-cigarette usage			
E-cigarettes used while in hospital, N (%)			
No	4 (23.5)	4 (19.0)	8 (21.1)
Yes	13 (76.5)	17 (81.0)	30 (78.9)
Frequency of e-cigarette usage, N (%)			
Less than once a week	0 (0.0)	3 (14.3)	3 (7.9)
Less than daily, but more than once a week	0 (0.0)	1 (4.8)	1 (2.6)
Every day	13 (76.5)	13 (61.9)	26 (68.4)
Not applicable	4 (23.5)	4 (19.0)	8 (21.1)
Length of e-cigarette usage while in hospital, N (%)			
Less than one week	1 (5.9)	2 (9.5)	3 (7.9)
1-2 weeks	0 (0.0)	3 (14.3)	3 (7.9)
2-3 weeks	2 (11.8)	2 (9.5)	4 (10.5)
3-4 weeks	0 (0.0)	5 (23.8)	5 (13.2)
1-2 months	3 (17.6)	2 (9.5)	5 (13.2)
2-3 months	3 (17.6)	1 (4.8)	4 (10.5)
3 months or more	4 (23.5)	2 (9.5)	6 (15.8)
Not applicable	4 (23.5)	4 (19.0)	8 (21.1)
Type of e-cigarette used (not mutually exclusive), N (%)			
Single-use - Disposable	11 (64.7)	15 (71.4)	26 (68.4)
Rechargeable - Pre-filled pods or cartridges	3 (17.6)	2 (9.5)	5 (13.2)
Rechargeable - Refillable (Tank)	0 (0.0)	1 (4.8)	1 (2.6)
PHQ-9			
N (% data available)	17 (100.0)	21 (100.0)	38 (100.0)
Mean (SD)	12.5 (7.2)	11.8 (7.0)	12.1 (7.0)
Median	12	10	12
Min, Max	0, 26	1, 27	0, 27
GAD-7			
N (% data available)	17 (100.0)	21 (100.0)	38 (100.0)
Mean (SD)	9.8 (6.8)	9.0 (5.4)	9.3 (6.0)
Median	12	9	9

Min, Max	0, 19	0, 18	0, 19
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4 Intervention Delivery

Table 8: Information on delivery of sessions. A total of 238 sessions were recorded, however 36 sessions took place outside of the SCEPTRE intervention and were not included in the results.

	Session Records (N=202)
Session details	
Session records	
Total number of session records, n	202
Total number of sessions attended, n (% of session records)	180 (89.1)
Method of session delivery, n (% of sessions attended)	
Phone call	149 (82.8)
Face to face	15 (8.3)
Missing	16 (8.9)
Average length of sessions, minutes	
n	202
Mean (SD)	21.1 (19.0)
Median (IQR)	10 (6 – 30)
Min, Max	1, 90

Table 9: Information on the support offered and accepted by participants.

	Intervention Participants (N=17)
Support details	
Participants with session records, n (%)	14 (82.4)
My-try kit support	
Offered at least once, n (%)	14 (82.4)
Accepted at least once, n (% of offered)	14 (100.0)
Motivational texts support	
Offered at least once, n (%)	13 (76.5)
Accepted at least once, n (% of offered)	11 (84.6)
Smoking app support	
Offered at least once, n (%)	13 (76.5)
Accepted at least once, n (% of offered)	9 (69.2)
Reasons for not accepting support	
Motivational texts support, n (% of two who declined support)	
No reason given	2 (100.0)
Smoking app support, n (% of four who declined support)	
No reason given	2 (50.0)
Participant stopped smoking	1 (25.0)
Participant does not have a smart phone	1 (25.0)

5 Primary Analysis

5.1 Recruitment

Table 10: Monthly recruitment presented overall. Recruitment started on the 23rd of January 2024 and closed on the 13th of July 2024.

Month	Overall (N=38)
January	0
February	2
March	7
April	1
May	10
June	10
July	8

Figure 2: Monthly recruitment graph presented overall.

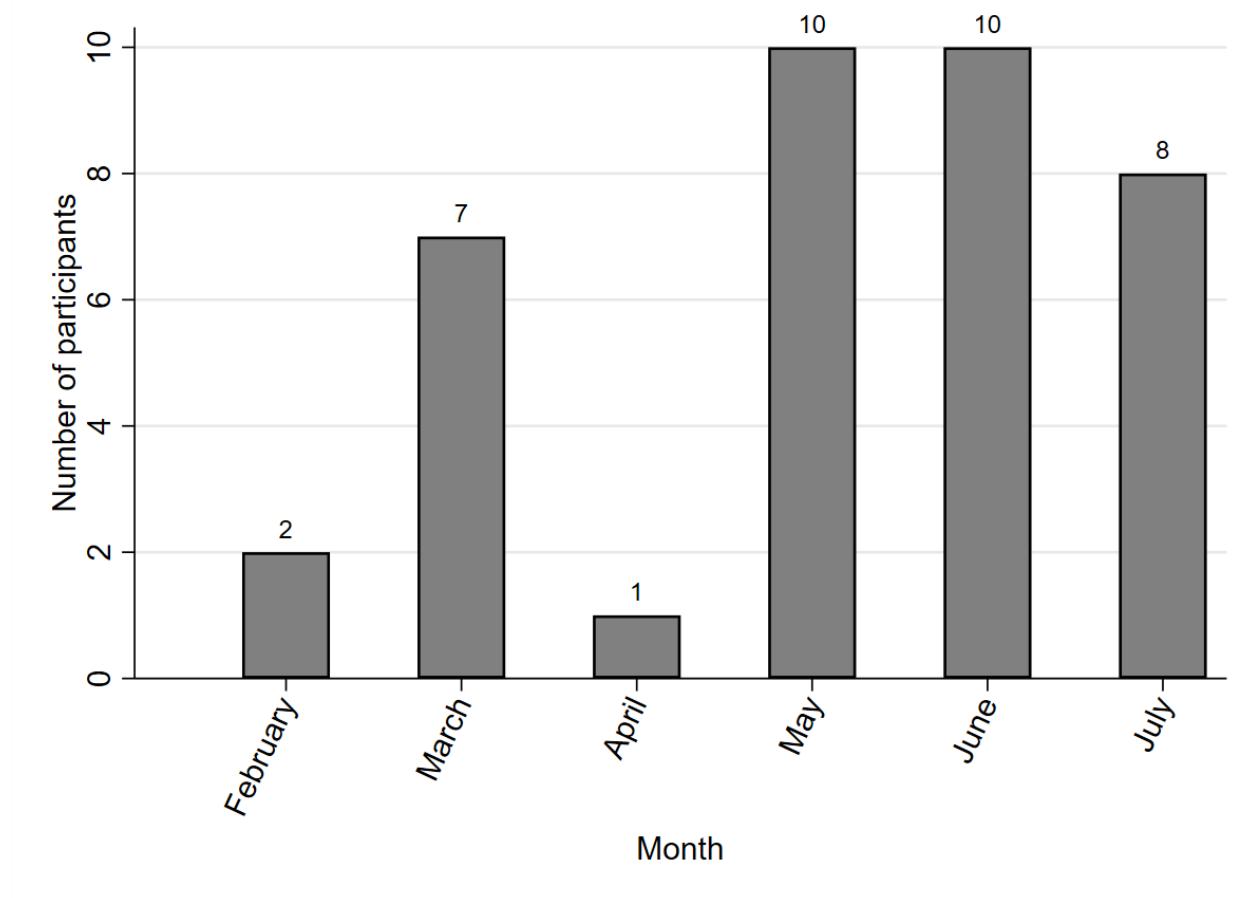


Table 11: Recruitment rate of those eligible presented by site, together with an estimate of overall recruitment rate together with the corresponding 95% confidence interval.

Site ID	Site name	Number eligible, N	Number recruited, N	Recruitment rate of those eligible, % (95% CI)
100	Leeds & York Partnership NHS FT	68	9	13.2 (6.2 - 23.6)
106	Leicestershire Partnership NHS	20	6	30.0 (11.9 - 54.3)
107	Hertfordshire Partnership University NHS FT	10	8	80.0 (44.4 - 97.5)
104	Derbyshire Healthcare NHS FT	71	8	11.3 (5.0 - 21.0)
105	East London NHS FT	16	2	12.5 (1.6 - 38.3)
103	Oxfordshire Health NHS FT	11	5	45.5 (16.7 - 76.6)
Total		196	38	19.4 (14.1 - 25.6)

5.2 Retention

Table 12: Information on the collection of participant questionnaires. The primary follow-up is categorised into 4,5,6-month follow-ups as well as a combined figure.

	SCEPTRE intervention	Usual Care	Overall
	N=17	N=21	N=38
3-month questionnaire returned, N (%)			
Yes	7 (41.2)	13 (61.9)	20 (52.6)
No	10 (58.8)	8 (38.1)	18 (47.4)
4-month questionnaire returned, N (%)			
N due at 4 months (%)	8 (47.1)	8 (38.1)	16 (42.1)
Yes	5 (62.5)	3 (37.5)	8 (50.0)
No	3 (37.5)	5 (62.5)	8 (50.0)
5-month questionnaire returned, N (%)			
N due at 5 months (%)	3 (17.6)	4 (19.0)	7 (18.4)
Yes	0 (0.0)	1 (25.0)	1 (14.3)
No	3 (100.0)	3 (75.0)	6 (85.7)
6-month questionnaire returned, N (%)			
N due at 6 months (%)	6 (35.3)	9 (42.9)	15 (39.5)
Yes	1 (16.7)	3 (33.3)	4 (26.7)
No	5 (83.3)	6 (66.7)	11 (73.3)
4-, 5- and 6-month questionnaire combined return, N (%)			
Yes	6 (35.3)	7 (33.3)	13 (34.2)
No	11 (64.7)	14 (66.7)	25 (65.8)

Table 13: The return of the primary outcome participant questionnaires summarised by site, together with an estimate of the overall retention rate together with the corresponding 95% confidence interval.

Site ID	Site name	Number randomised, N	Number M6 forms returned, N	Retention rate, % (95% CI)
100	Leeds & York Partnership NHS FT	9	2	22.2 (2.8 - 60.0)
106	Leicestershire Partnership NHS	6	0	0.0 (0.0 - 45.9)
107	Hertfordshire Partnership University NHS FT	8	4	50.0 (15.7 - 84.3)
104	Derbyshire Healthcare NHS FT	8	5	62.5 (24.5 - 91.5)
105	East London NHS FT	2	0	0.0 (0.0 - 84.2)
103	Oxfordshire Health NHS FT	5	2	40.0 (5.3 - 85.3)
Total		38	13	34.2 (19.6 - 51.4)

5.3 Progression Criteria

Table 14: Pilot Progression Criteria

Criterion	Target at end of Internal Pilot	Current Status	Green	Amber	Red
Participant Recruitment	64 participants recruited	38 (60%)	100% (64)	60-99% (38-64)	<60% (<38)
Participant Retention	>= 80% of primary outcome data available	13/38 (34.2%)	80-100% (51-64)	60-80% (38-51)	<60% (<38)
Trusts Enrolled	8	6 (80.0%)	80-100% (7-8)	60-80% (5-6)	<60% (<5)
CO Collection*	>=75% of self-reported quitters	2/3 (66.6%)	75-100%	50-75%	<50%

*Sample not large enough to provide accurate judgement for this criterion.

6 Secondary Analyses

6.1 Descriptive Summaries of Outcomes

Table 15: PROMs at 3-months post-randomisation summarised descriptively by treatment group.

	SCEPTRE intervention	Usual Care	Overall
	N=7	N=13	N=20
7-day point prevalence			
Self-reported as abstinent, N (%)			
No	4 (57.1)	13 (100.0)	17 (85.0)
Yes	3 (42.9)	0 (0.0)	3 (15.0)
CO-validated as abstinent, N (%)			
No	5 (71.4)	13 (100.0)	18 (90.0)
Yes	2 (28.6)	0 (0.0)	2 (10.0)
Continuous abstinence			
Length of time since last smoked, N (%)			
0-7 days ago	4 (57.1)	13 (100.0)	17 (85.0)
1 - 2 months ago	2 (28.6)	0 (0.0)	2 (10.0)
Not applicable	1 (14.3)	0 (0.0)	1 (5.0)
CO measurement			
CO reading collected, N (%)			
Yes	2 (28.6)	0 (0.0)	2 (10.0)
No	5 (71.4)	13 (100.0)	18 (90.0)
CO reading, N (%)			
0-4 ppm	2 (28.6)	0 (0.0)	2 (10.0)
Not taken	5 (71.4)	13 (100.0)	18 (90.0)
HSI			
Time until first cigarette after waking up, N (%)			
Within 5 minutes	2 (28.6)	1 (7.7)	3 (15.0)
6-30 minutes	2 (28.6)	8 (61.5)	10 (50.0)
31-60 minutes	1 (14.3)	1 (7.7)	2 (10.0)
After 60 minutes	1 (14.3)	3 (23.1)	4 (20.0)
Missing	1 (14.3)	0 (0.0)	1 (5.0)
Cigarettes typically smoked each day, N (%)			
10 or fewer	5 (71.4)	7 (53.8)	12 (60.0)
11-20 cigarettes	1 (14.3)	4 (30.8)	5 (25.0)
21-30 cigarettes	0 (0.0)	1 (7.7)	1 (5.0)
31 or more	0 (0.0)	1 (7.7)	1 (5.0)
Missing	1 (14.3)	0 (0.0)	1 (5.0)
HSI Overall Score			
N (% data available)	6 (85.7)	13 (100.0)	19 (95.0)
Mean (SD)	2.0 (1.3)	2.2 (1.6)	2.2 (1.5)
Median	2	2	2
Min, Max	0, 3	0, 6	0, 6
Strength of urges to smoke			
Frequency of urges to smoke in the past 24hrs, N (%)			
Not at all	3 (42.9)	0 (0.0)	3 (15.0)

A little of the time	1 (14.3)	5 (38.5)	6 (30.0)
Some of the time	0 (0.0)	1 (7.7)	1 (5.0)
A lot of the time	2 (28.6)	4 (30.8)	6 (30.0)
All of the time	1 (14.3)	3 (23.1)	4 (20.0)
Strength of urges in general, N (%)			
Light	4 (57.1)	3 (23.1)	7 (35.0)
Moderate	1 (14.3)	4 (30.8)	5 (25.0)
Strong	1 (14.3)	4 (30.8)	5 (25.0)
Very strong	0 (0.0)	1 (7.7)	1 (5.0)
Extremely strong	1 (14.3)	1 (7.7)	2 (10.0)
Strength of urges to smoke overall Score			
N (% data available)	7 (100.0)	13 (100.0)	20 (100.0)
Mean (SD)	5.7 (3.5)	7.1 (2.5)	6.6 (2.9)
Median	4	7	6
Min, Max	3, 12	4, 12	3, 12
Motivation to stop smoking			
Importance, N (%)			
Not at all important	0 (0.0)	4 (30.8)	4 (20.0)
Quite important	2 (28.6)	6 (46.2)	8 (40.0)
Very important	2 (28.6)	3 (23.1)	5 (25.0)
Desperately important	3 (42.9)	0 (0.0)	3 (15.0)
Determination, N (%)			
Not all that determined	0 (0.0)	4 (30.8)	4 (20.0)
Quite determined	3 (42.9)	7 (53.8)	10 (50.0)
Very determined	0 (0.0)	2 (15.4)	2 (10.0)
Extremely determined	4 (57.1)	0 (0.0)	4 (20.0)
Chance, N (%)			
Very low	0 (0.0)	3 (23.1)	3 (15.0)
Low	0 (0.0)	3 (23.1)	3 (15.0)
Not very high	0 (0.0)	5 (38.5)	5 (25.0)
Quite high	2 (28.6)	0 (0.0)	2 (10.0)
Very high	4 (57.1)	2 (15.4)	6 (30.0)
Extremely high	1 (14.3)	0 (0.0)	1 (5.0)
Motivation to stop smoking overall Score			
N (% data available)	7 (100.0)	13 (100.0)	20 (100.0)
Mean (SD)	11.1 (2.4)	6.4 (2.4)	8.1 (3.3)
Median	12	6	8
Min, Max	8, 14	3, 11	3, 14
Reasons for motivation, N (%)			
Because my health is already suffering	1 (14.3)	1 (7.7)	2 (10.0)
Because I am worried about my future health	4 (57.1)	6 (46.2)	10 (50.0)
Because smoking costs too much	2 (28.6)	0 (0.0)	2 (10.0)
For my family's health	0 (0.0)	2 (15.4)	2 (10.0)
Other (please specify):	0 (0.0)	4 (30.8)	4 (20.0)
E-cigarette usage			
E-cigarettes used while in hospital, N (%)			
No	0 (0.0)	6 (46.2)	6 (30.0)
Yes	7 (100.0)	7 (53.8)	14 (70.0)
Frequency of e-cigarette usage, N (%)			
Less than once a week	1 (14.3)	1 (7.7)	2 (10.0)
Less than daily, but more than once a week	1 (14.3)	0 (0.0)	1 (5.0)
Every day	5 (71.4)	6 (46.2)	11 (55.0)

Not applicable	0 (0.0)	6 (46.2)	6 (30.0)
Length of e-cigarette usage while in hospital, N (%)			
Less than one week	1 (14.3)	0 (0.0)	1 (5.0)
2-3 weeks	1 (14.3)	1 (7.7)	2 (10.0)
2-3 months	5 (71.4)	6 (46.2)	11 (55.0)
Not applicable	0 (0.0)	6 (46.2)	6 (30.0)
Type of e-cigarette used (not mutually exclusive), N (%)			
Single-use - Disposable	4 (57.1)	1 (7.7)	5 (25.0)
Rechargeable - Pre-filled pods or cartridges	1 (14.3)	2 (15.4)	3 (15.0)
Rechargeable - Refillable (Tank)	0 (0.0)	1 (7.7)	1 (5.0)
Rechargeable - Modified (Mods)	2 (28.6)	0 (0.0)	2 (10.0)
PHQ-9			
N (% data available)	7 (100.0)	13 (100.0)	20 (100.0)
Mean (SD)	11.4 (7.3)	8.5 (7.1)	9.6 (7.1)
Median	9	7	8
Min, Max	2, 25	0, 27	0, 27
GAD-7			
N (% data available)	7 (100.0)	13 (100.0)	20 (100.0)
Mean (SD)	11.4 (7.3)	7.5 (6.7)	8.9 (7.0)
Median	11	6	8
Min, Max	1, 21	0, 20	0, 21

Table 16: PROMs at 6-months post-randomisation summarised descriptively by treatment group.

	SCEPTRE intervention	Usual Care	Overall
	N=6	N=7	N=13
7-day point prevalence			
Self-reported as abstinent, N (%)			
No	4 (66.7)	6 (85.7)	10 (76.9)
Yes	2 (33.3)	1 (14.3)	3 (23.1)
CO-validated as abstinent, N (%)			
No	4 (66.7)	7 (100.0)	11 (84.6)
Yes	2 (33.3)	0 (0.0)	2 (15.4)
Continuous abstinence			
Length of time since last smoked, N (%)			
0-7 days ago	4 (66.7)	6 (85.7)	10 (76.9)
8 days - 1 month ago	0 (0.0)	1 (14.3)	1 (7.7)
Not applicable	2 (33.3)	0 (0.0)	2 (15.4)
CO measurement			
CO reading collected, N (%)			
Yes	2 (33.3)	1 (14.3)	3 (23.1)
No	4 (66.7)	6 (85.7)	10 (76.9)
CO reading, N (%)			
0-4 ppm	2 (33.3)	0 (0.0)	2 (15.4)
>=10 ppm	0 (0.0)	1 (14.3)	1 (7.7)
Not taken	4 (66.7)	6 (85.7)	10 (76.9)
HSI			
Time until first cigarette after waking up, N (%)			
Within 5 minutes	2 (33.3)	2 (28.6)	4 (30.8)
6-30 minutes	1 (16.7)	2 (28.6)	3 (23.1)
31-60 minutes	1 (16.7)	1 (14.3)	2 (15.4)
After 60 minutes	0 (0.0)	2 (28.6)	2 (15.4)
Missing	2 (33.3)	0 (0.0)	2 (15.4)
Cigarettes typically smoked each day, N (%)			
10 or fewer	3 (50.0)	5 (71.4)	8 (61.5)
11-20 cigarettes	1 (16.7)	1 (14.3)	2 (15.4)
31 or more	0 (0.0)	1 (14.3)	1 (7.7)
Missing	2 (33.3)	0 (0.0)	2 (15.4)
HSI Overall Score			
N (% data available)	4 (66.7)	7 (100.0)	11 (84.6)
Mean (SD)	2.5 (1.0)	2.1 (2.1)	2.3 (1.7)
Median	3	2	3
Min, Max	1, 3	0, 6	0, 6
Strength of urges to smoke			
Frequency of urges to smoke in the past 24hrs, N (%)			
Not at all	2 (33.3)	0 (0.0)	2 (15.4)
A little of the time	0 (0.0)	3 (42.9)	3 (23.1)
Some of the time	4 (66.7)	1 (14.3)	5 (38.5)
A lot of the time	0 (0.0)	1 (14.3)	1 (7.7)
All of the time	0 (0.0)	2 (28.6)	2 (15.4)

Strength of urges in general, N (%)			
Zero/None	3 (50.0)	1 (14.3)	4 (30.8)
Light	1 (16.7)	0 (0.0)	1 (7.7)
Moderate	2 (33.3)	2 (28.6)	4 (30.8)
Strong	0 (0.0)	4 (57.1)	4 (30.8)
Strength of urges to smoke overall Score			
N (% data available)	6 (100.0)	7 (100.0)	13 (100.0)
Mean (SD)	4.2 (1.8)	6.9 (2.6)	5.6 (2.6)
Median	4	6	6
Min, Max	2, 6	3, 10	2, 10
Motivation to stop smoking			
Importance, N (%)			
Not at all important	1 (16.7)	3 (42.9)	4 (30.8)
Quite important	2 (33.3)	2 (28.6)	4 (30.8)
Very important	2 (33.3)	1 (14.3)	3 (23.1)
Desperately important	1 (16.7)	1 (14.3)	2 (15.4)
Determination, N (%)			
Not all that determined	0 (0.0)	3 (42.9)	3 (23.1)
Quite determined	5 (83.3)	2 (28.6)	7 (53.8)
Very determined	0 (0.0)	1 (14.3)	1 (7.7)
Extremely determined	1 (16.7)	1 (14.3)	2 (15.4)
Chance, N (%)			
Very low	0 (0.0)	2 (28.6)	2 (15.4)
Low	0 (0.0)	1 (14.3)	1 (7.7)
Not very high	1 (16.7)	1 (14.3)	2 (15.4)
Quite high	3 (50.0)	1 (14.3)	4 (30.8)
Very high	1 (16.7)	1 (14.3)	2 (15.4)
Extremely high	1 (16.7)	1 (14.3)	2 (15.4)
Motivation to stop smoking overall Score			
N (% data available)	6 (100.0)	7 (100.0)	13 (100.0)
Mean (SD)	9.2 (2.6)	7.1 (4.2)	8.1 (3.6)
Median	9	7	8
Min, Max	6, 14	3, 14	3, 14
Reasons for motivation, N (%)			
Because my health is already suffering	1 (16.7)	1 (14.3)	2 (15.4)
Because I am worried about my future health	1 (16.7)	3 (42.9)	4 (30.8)
Because smoking costs too much	3 (50.0)	0 (0.0)	3 (23.1)
Other (please specify):	1 (16.7)	3 (42.9)	4 (30.8)
E-cigarette usage			
E-cigarettes used while in hospital, N (%)			
No	1 (16.7)	2 (28.6)	3 (23.1)
Yes	5 (83.3)	5 (71.4)	10 (76.9)
Frequency of e-cigarette usage, N (%)			
Less than once a week	0 (0.0)	1 (14.3)	1 (7.7)
Less than daily, but more than once a week	1 (16.7)	1 (14.3)	2 (15.4)
Every day	4 (66.7)	3 (42.9)	7 (53.8)
Not applicable	1 (16.7)	2 (28.6)	3 (23.1)
Length of e-cigarette usage, N (%)			
Less than one week	1 (16.7)	1 (14.3)	2 (15.4)
1-2 months	0 (0.0)	1 (14.3)	1 (7.7)
3-4 months	2 (33.3)	0 (0.0)	2 (15.4)
5-6 months	2 (33.3)	3 (42.9)	5 (38.5)

Not applicable	1 (16.7)	2 (28.6)	3 (23.1)
Main type of e-cigarette used, N (%)			
Single-use - Disposable	3 (50.0)	2 (28.6)	5 (38.5)
Rechargeable - Pre-filled pods or cartridges	1 (16.7)	0 (0.0)	1 (7.7)
Rechargeable - Refillable (Tank)	1 (16.7)	3 (42.9)	4 (30.8)
Missing	1 (16.7)	2 (28.6)	3 (23.1)
PHQ-9			
N (% data available)	6 (100.0)	7 (100.0)	13 (100.0)
Mean (SD)	16.3 (6.1)	11.0 (9.9)	13.5 (8.5)
Median	19	8	17
Min, Max	4, 20	1, 27	1, 27
GAD-7			
N (% data available)	6 (100.0)	7 (100.0)	13 (100.0)
Mean (SD)	12.3 (3.9)	8.6 (7.9)	10.3 (6.4)
Median	14	7	9
Min, Max	6, 15	1, 21	1, 21

6.2 Adverse Events

Table 17: Number of non-serious adverse events per participant presented overall and by treatment group.

	SCEPTRE intervention	Usual Care	Overall
	N=17	N=21	N=38
One or more NSAEs, N (%)			
Yes	1 (5.9)	2 (9.5)	3 (7.9)
No	16 (94.1)	19 (90.5)	35 (92.1)
Number of NSAEs per participant, N (%)			
0	16 (94.1)	19 (90.5)	35 (92.1)
1	1 (5.9)	2 (9.5)	3 (7.9)
Days between randomisation and onset of NSAE			
N	1	2	3
Mean (SD)	71.0 (0.0)	48.0 (28.3)	55.7 (24.0)
Median	71	48	68
Min, Max	71, 71	28, 68	28, 71
Study action taken, N (%)			
None	1 (100.0)	2 (100.0)	3 (100.0)
Relationship to study treatment, N (%)			
Not related	1 (100.0)	2 (100.0)	3 (100.0)

Table 18: Number of serious adverse events per participant presented overall and by treatment group.

	SCEPTRE intervention	Usual Care	Overall
	N=17	N=21	N=38
One or more SAEs, N (%)			
Yes	6 (35.3)	4 (19.0)	10 (26.3)
No	11 (64.7)	17 (81.0)	28 (73.7)
Number of SAEs per participant, N (%)			
0	11 (64.7)	17 (81.0)	28 (73.7)
1	4 (23.5)	3 (14.3)	7 (18.4)
2	2 (11.8)	0 (0.0)	2 (5.3)
3	0 (0.0)	1 (4.8)	1 (2.6)
Days between randomisation and onset of SAE			
N (% data available)	6 (35.3)	4 (19.0)	10 (26.3)
Mean (SD)	60.0 (20.9)	115.8 (46.9)	82.3 (42.5)
Median	60	110	73
Min, Max	36, 88	66, 178	36, 178
Study action taken, N (%)			
Study treatment interrupted/halted	4 (66.7)	0 (0.0)	4 (40.0)
None	2 (33.3)	4 (100.0)	6 (60.0)
Relationship to study treatment, N (%)			
Not related	3 (50.0)	4 (100.0)	7 (70.0)
Unlikely to be related	3 (50.0)	0 (0.0)	3 (30.0)

Table 19: Non-serious adverse event details.

Participant ID	Site ID	Allocation	Onset date	Action Taken	Related	Outcome	Description
1040001	104	Intervention Delivery	22/5/2024	None	Not related	Resolved	During the 3 month follow up it was disclosed by the participant that on 22/05/2024 he had a 999 call and ambulance from the acute mental unit- the Radbourne Unit due to experiencing chest pain. The participant was taken to A&E where he was monitored and had the necessary tests required. The participant was discharged back to the Radbourne Unit the same day having recovered from this event.
1060005	106	Usual Care	4/6/2024	None	Not related	Resolved	Attended A and E as feeling suicidal on the 4th June. Self-discharged after a couple of hours. No follow up recorded. Participant reported they would engage with the crisis team however they were discharged from the crisis team for not engaging.
1000009	100	Usual Care	17/9/2024	None	Not related	Resolved	Participant has had 9 seizures over the last few days, 7 were in St James' Hospital before he was discharged. He was discharged at 6pm on the 17/09/24 and returned to The Becklin Centre, at 11pm on 17/09/24 he then had a seizure while in the courtyard at the Becklin Centre and vomited. Another service user moved him to his side so that he did not choke on the vomit. An ambulance was called to examine him, and he was taken to A&E.

Table 20: Serious adverse event details

Participant ID	Site ID	Allocation	Onset date	Action Taken	Related	Outcome	Description
1040002	104	Intervention Delivery	23/4/2024	Study treatment interrupted / halted	Not related	Resolved	Person experiencing a relapse in their mental health condition with worsening symptoms of hearing voices telling them to harm themselves. Person struggling with the care of their children and their mother also struggling with the care of them and their children at home. Person expressing that their medications were not working, and they were feeling suicidal due to changes in medications. Person recently took an overdose of paracetamol and ligatured at the emergency department. Person was admitted to the

							Hartington unit informally due to their suicide risk on 23/04/24
1000002	100	Intervention Delivery	26/4/2024	Study treatment interrupted / halted	Not related	Resolved	Participant has a diagnosis of bipolar disorder and was discharged from her last admission on a CTO. She has been readmitted due to a relapse of her symptoms, manic behaviour, delusional beliefs / hallucinations. She had refused her depot while in the community.
1040001	104	Intervention Delivery	29/4/2024	None	Unlikely to be related	Resolved	During the participants 3 month follow up it was disclosed by the participant that they attended the A&E department on 29/04/2024 due to taking an overdose of paracetamol. The participant was monitored by staff in A&E and was given the necessary treatment. He was then discharged the next day back to ward 36 at the Radbourne Unit where he had been residing since the start of his participation in the study.
1000001	100	Usual Care	23/5/2024	None	Not related	Resolved	The participant's CTO has been revoked as she is presenting as unwell, and the psychiatrist believes that she needs a period of assessment and treatment in hospital to stabilise her mental state and manage risks.
1040004	104	Intervention Delivery	19/6/2024	Study treatment interrupted / halted	Unlikely to be related	Death	Upon reviewing the participants notes on 21/06/2024 it became apparent that the participant ligatured at home on 19/06/2024 and subsequently passed away the same day at home.
1060004	106	Usual Care	18/7/2024	None	Not related	Resolved	Known schizophrenic disorder. Admitted under section 17a for medication. Previously at home with community support. Community team noticed they were becoming increasingly dishevelled, disengaging with staff and becoming more aggressive. Admitted for depo. Compliant in hospital post medication so returned home with community support.
1040001	104	Intervention Delivery	29/7/2024	None	Not related	Resolved	Participant was taken to A&E via ambulance following taking an overdose of Paracetamol. Participant had bloods taken to measure the level of paracetamol in the body and was then taken to a ward to receive the necessary treatment and was discharged 2 days later.
1030002	103	Intervention Delivery	2/9/2024	Study treatment interrupted / halted	Not related	Ongoing	Participant admitted to psychiatric hospital. Extra info: Participant had last contact with Niamh Hunniford for a behavioural support call on 18th July 2024. After this, the participant did not respond to weekly calls & texts from Niamh. Niamh contacted the participant's care coordinator

							on 9th August 2024 however they had no response either. Niamh continued to call on a weekly basis with no response from the participant & clinic notes were updated. Participant was admitted to a psychiatric hospital under section 3 on 2nd September 2024. NH will contact participant if discharged before intervention deadline of 7th October.
1000009	100	Usual Care	15/9/2024	None	Not related	Resolved	Admitted to St James University Hospital J28 due to witnessed tonic-clonic seizures. Reports having seizures since childhood but has no formal diagnosis of epilepsy.
1070005	107	Intervention Delivery	17/9/2024	None	Unlikely to be related	Resolved	Participant attempted to jump from a multi-storey car park and ingested peanuts to which she has an allergy for (eaten to self-harm)
1000009	100	Usual Care	1/10/2024	None	Not related	Resolved	Patient was taken to A&E in an ambulance following an overdose. He was then admitted to hospital and treated for the overdose.
1070005	107	Intervention Delivery	2/10/2024	Other	Unlikely to be related	Resolved	Participant ingested batteries as a form of self-harm and was subsequently sectioned. Participant also had a non-epileptic seizure whilst being on the inpatient unit (12/10/2024)
1040003	104	Usual Care	27/10/2024	None	Not related	Resolved	Participant reported he had been to hospital for his mental health and had been discharged home. Participant was minimal with regards describing this event. On checking the notes for details, it appears that the person was taken to A&E in an ambulance on 27/10/24 after calling 999 and reporting taking an intentional overdose of 64x 500mg paracetamol tablets. Notes indicate that he was admitted to ward 5 at Queens hospital Burton on the 28/10/24. Whilst in hospital the participant had 4 bags of NAC as treatment for the overdose. Notes indicate he was discharged on the 29/10/24 and followed up by the crisis team on the 30/10/24. Participant is now receiving daily visits from the crisis team.
1000009	100	Usual Care	1/11/2024	None	Not related	Resolved	The participant took an overdose in the early hours of the morning which consisted of 96 paracetamol, 32x300mg Aspirin, 7x7.5mg Zopiclone and 7x50mg Sertraline. They then tried to call the crisis team which didn't pick up and so put them through to YAS. He was taken to A&E via ambulance and admitted, they spent 3 nights in hospital.

6.3 Withdrawals

Table 21: Information on withdrawals presented overall and by treatment group.

	SCEPTRE intervention	Usual Care	Overall
	N=17	N=21	N=38
Withdrew, N (%)			
Yes	7 (41.2)	1 (4.8)	8 (21.1)
No	10 (58.8)	20 (95.2)	30 (78.9)
Time between randomisation and withdrawal (Days)			
N (%)	7 (41.2)	1 (4.8)	8 (21.1)
Mean (SD)	64.3 (52.3)	101.0 (.)	68.9 (50.1)
Median	44	101	48
Min, Max	17, 144	101, 101	17, 144
Type of withdrawal, N (%)			
Deceased	1 (5.9)	0 (0.0)	1 (2.6)
Follow-up Withdrawal	1 (5.9)	1 (4.8)	2 (5.3)
Full Withdrawal	3 (17.6)	0 (0.0)	3 (7.9)
Treatment Withdrawal	2 (11.8)	0 (0.0)	2 (5.3)

Table 22: Participant withdrawal details

Site	Allocation	Type of Withdrawal	Date Withdrawn	Reason for withdrawal (if provided)
Leicestershire Partnership NHS	Intervention Delivery	Full Withdrawal	25/3/2024	Experiencing anxiety and stress at point of discharge to home
Leeds & York Partnership NHS FT	Intervention Delivery	Treatment Withdrawal	10/4/2024	Does not wish to take part in the intervention
Derbyshire Healthcare NHS FT	Intervention Delivery	Treatment Withdrawal	15/4/2024	Participant no longer wishes to cut down or stop smoking
Derbyshire Healthcare NHS FT	Intervention Delivery	Full Withdrawal	8/5/2024	Participant is very unwell mentally and has decided that taking part in the study in addition to her mental health problems has become too much for her to handle. She has therefore decided to completely withdraw from the study.
Derbyshire Healthcare NHS FT	Intervention Delivery	Deceased	21/6/2024	Participant has died
Leeds & York Partnership NHS FT	Intervention Delivery	Full Withdrawal	28/6/2024	The participant is severely unwell and currently lacking capacity and insight. Due to lack of capacity, and based on section 11.6 of the protocol, it is appropriate to withdraw this participant from the

trial.				
Hertfordshire Partnership University NHS FT	Intervention Delivery	Follow-up Withdrawal	11/10/2024	Participant reports not having time anymore for the study due to having ongoing life stressors.
Hertfordshire Partnership University NHS FT	Usual Care	Follow-up Withdrawal	14/10/2024	No longer interested in participating in the study.