1. Participant Flow

A total of 88 patients were assessed for eligibility; 72 were randomised, 36 to the intervention arm and 36 to the control arm. Follow-up at 1 month was completed by 70 of 72 participants (97%).

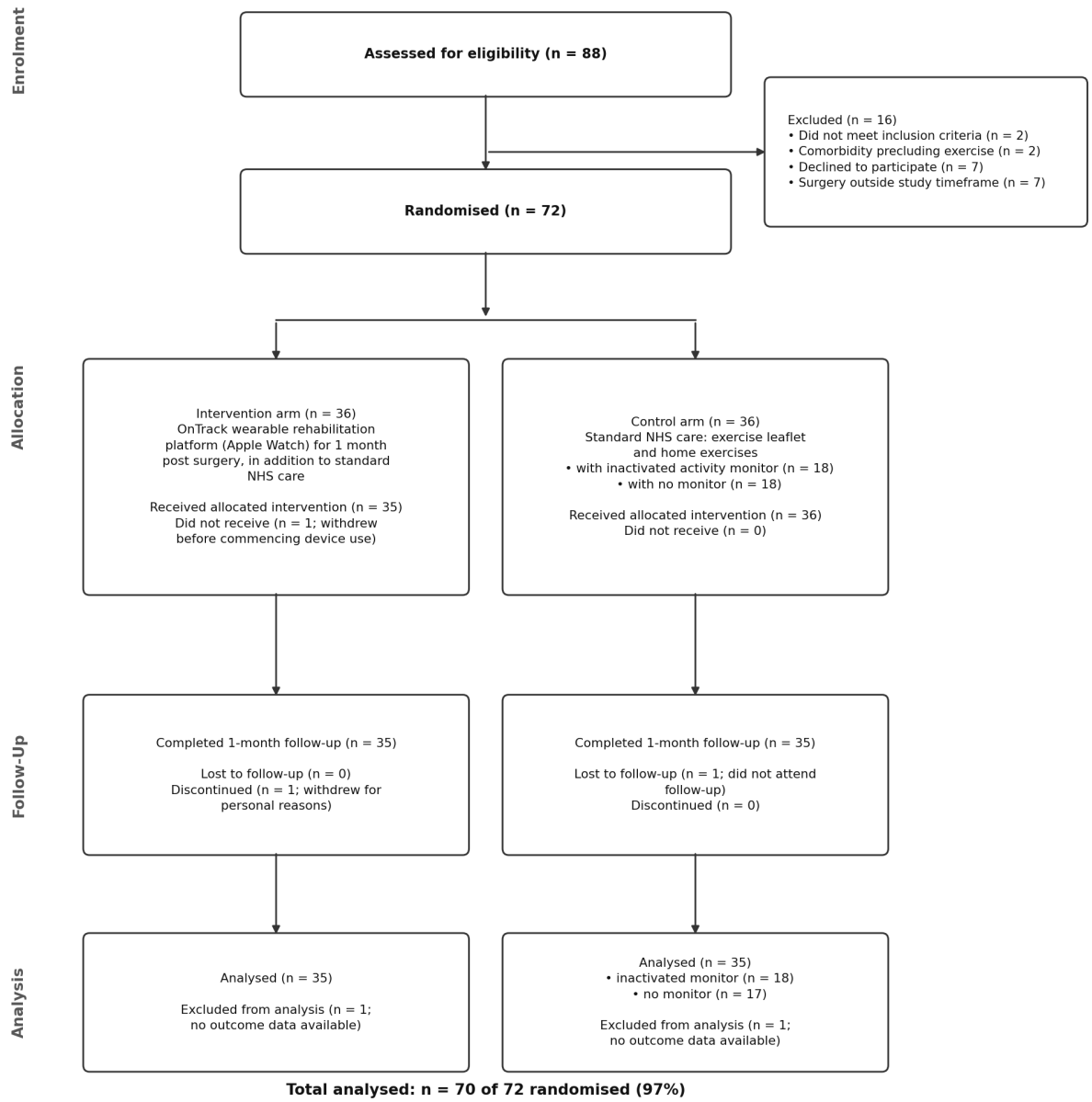

Figure 1. CONSORT flow diagram.

2. Baseline Characteristics

Table 2. Baseline demographic and surgical characteristics of the analysed population (n=70).

Characteristic		Intervention arm (n=35)	Control arm (n=35)	p
Age, years	Mean (SD)	59.3 (9.7)	59.6 (11.6)	NS
Sex	Female : male	35 : 0	35 : 0	NS
Handedness	Right : left	31 : 4	31 : 4	NS
BMI, kg/m²	Mean (SD)	26.2 (7.3)	26.4 (5.2)	NS
Axillary surgery	SLNB	29 (83%)	29 (83%)	NS
	TAD	1 (3%)	0	NS
	ALND	5 (14%)	6 (17%)	NS
Breast surgery	Breast-conserving (total)	23 (66%)	24 (69%)	NS
	Wide local excision	20 (57%)	21 (60%)	NS
	Therapeutic mammoplasty	3 (9%)	3 (9%)	NS
	Mastectomy (total)	12 (34%)	11 (31%)	NS
	Simple mastectomy	6 (17%)	5 (14%)	NS
	DIEP reconstruction	5 (14%)	6 (17%)	NS
	TUG reconstruction	1 (3%)	0	NS

Baseline measures used in analysing the outcome measures

Baseline measure	Intervention arm (n=35)	Control arm (n=35)
Baseline DASH, EQ-5D-5L, EQ-5D VAS, pain VAS	Collected, 100% complete	Collected, 100% complete
Baseline shoulder ROM (goniometer) and strength (dynamometer)	Collected, 100% complete	Collected, 100% complete
Baseline body composition and arm circumference	Collected, 100% complete	Collected, 100% complete

3. Outcome Measures

All outcomes were assessed at baseline (1 week preoperatively) and at 1 month postoperatively unless otherwise stated.

Composition of the control arm

The control arm received standard NHS care (exercise leaflet and home exercises). Within that arm, 18 participants wore an inactivated activity monitor to track arm movement and 17 had no monitor.

Outcomes were first compared between these two control subgroups. No statistically significant difference was found between them for any outcome measure, objective or patient-reported. Wearing an inactivated monitor, without any feedback, did not alter outcomes relative to the leaflet alone.

The two subgroups are therefore reported together as a single control arm (n=35) throughout this section.

Primary outcome 1 - Patient perceptions, satisfaction and acceptability of the Wearable system

Measure	Intervention arm (n=35)	Control arm (n=35)
System Usability Scale, mean (SD)	91.5 (4.6); 95% CI 90-93	Not administered
SUS questionnaire completion	35/35 (100%)	Not applicable
Participants reporting satisfaction with the intervention (pre-specified acceptability threshold ≥80%)	35/35 (100%)	Not applicable

Primary outcome 2 - Postoperative upper-limb pain (pain visual analogue scale), change from baseline to 1 month

Outcome measure	Intervention arm (n=35)	Control arm (n=35)	P (exploratory)
Pain VAS (0-10; higher = more pain), change from baseline	0 (0 to 1)	4 (3 to 5)	<0.001

Primary outcome 3 - Postoperative upper-limb movement in the affected limb (DASH, goniometer range of motion, dynamometer strength), change from baseline to 1 month

Outcome measure	Intervention arm (n=35)	Control arm (n=35)	P (exploratory)
DASH score (0-100; higher = greater disability), change from baseline	1.4 (0.4 to 1.95)	8.3 (7.15 to 9.8)	<0.001
Shoulder range of motion at 1 month, % of preoperative baseline (goniometer)			
Flexion	98.9 (90.1-101.1)	78.7 (68.6-87.3)	<0.001
Extension	101.8 (94.8-102.5)	85.4 (80.0-94.3)	<0.001
Abduction	87.5 (76.9-99.7)	65.3 (55.2-78.1)	<0.001
Shoulder strength at 1 month, % of preoperative baseline (handheld dynamometer)			
Flexion	98.4 (95.4-105.1)	91.2 (88.6-93.9)	<0.001
Extension	101.1 (96.6-106.7)	92.0 (90.5-94.1)	<0.001
Abduction	96.5 (93.9-98.6)	89.4 (86.1-93.3)	<0.001

Primary outcome 4 - Health-related quality of life (EQ-5D-5L), change from baseline to 1 month

Outcome measure	Intervention arm (n=35)	Control arm (n=35)	P (exploratory)
EQ-5D-5L index (higher = better health), change from baseline	-0.015 (-0.027 to -0.009)	-0.064 (-0.079 to -0.051)	<0.001
EQ-5D visual analogue scale (0-100%), change from baseline	-5% (-5 to 0)	−10% (-10 to -5)	<0.001

4. Harms / Adverse Events

Adverse event	Classification	Intervention arm (n=35)	Control arm (n=35)
Death (any cause)	All-cause mortality	0 (0%)	0 (0%)
Any serious adverse event	Serious	0 (0%)	0 (0%)
Unplanned return to theatre	Serious	0 (0%)	0 (0%)
Lymphoedema (≥2 cm increase in arm circumference, or clinically suspected/confirmed)	Other	0 (0%)	0 (0%)
Device-related adverse event	Other	0 (0%)	0 (0%)

There were no deaths and no serious adverse events in either arm of this study.