Figure S1. Flowchart of recruitment

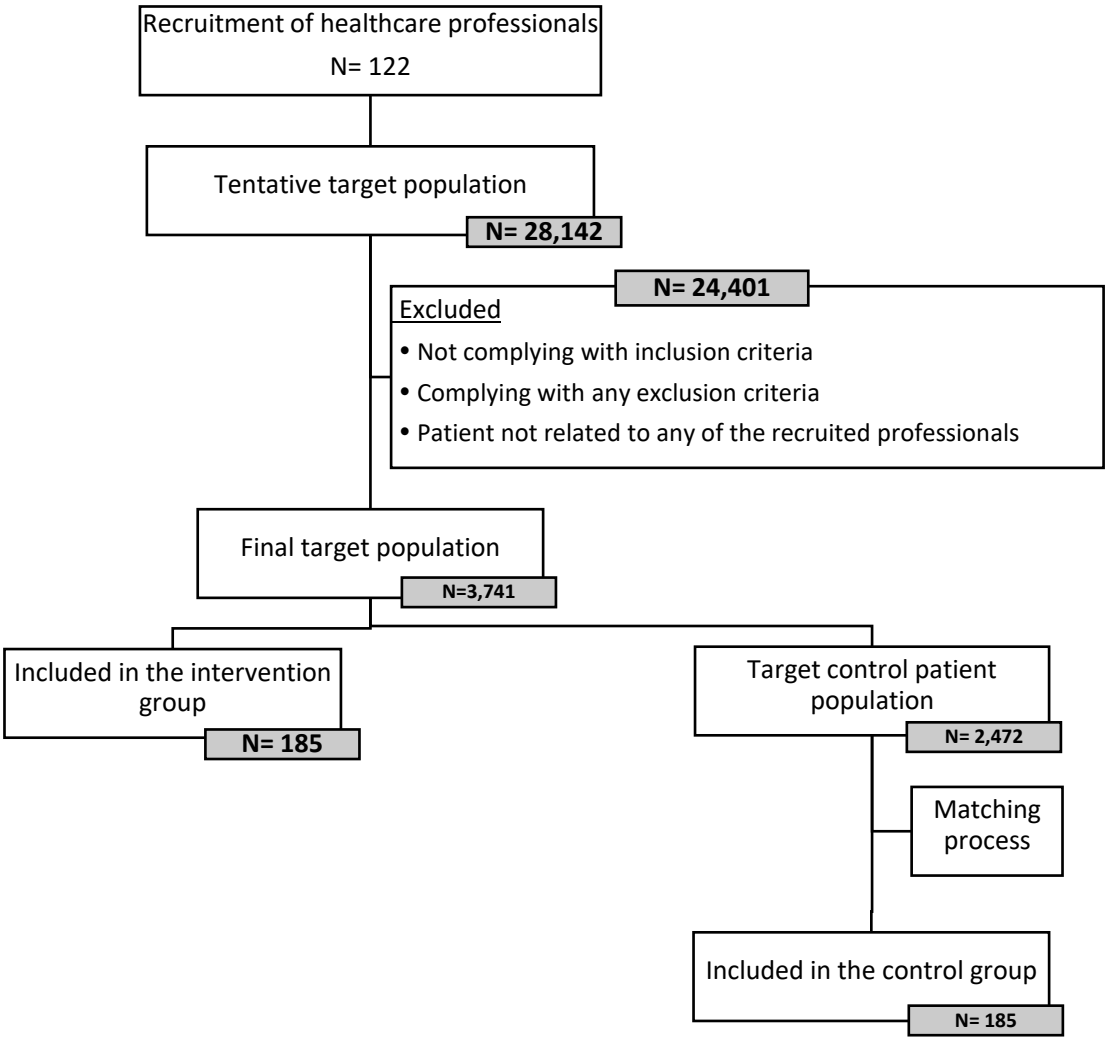

Table S1. Sensitivity analysis results: hurdle model coefficient estimates for the analysis of ADLIFE intervention effectiveness with and without data from UHCW

MODEL 1	**With UHCW (N=370)**		**Without UHCW (N=346)**	
Zero hurdle part (binomial with logit link)				
	$\hat{\alpha}$ (Std.Error)	p-value	$\hat{\alpha}$ (Std.Error)	p-value
Group: ADLIFE	-0.590 (0.279)	0.035*	-0.590 (0.279)	0.035*
Site[a]:				
Osakidetza	-1.173 (0.528)	0.026*	-1.173 (0.528)	0.026*
UHCW	-17.486 (1288.241)	0.989	NA	NA
OUH	-0.951 (0.303)	0.002*	-0.951 (0.303)	0.002*
Diagnosis[b]:				
COPD	-0.900 (0.400)	0.024*	-0.900 (0.400)	0.024*
COPD&CHF	-0.804 (0.435)	0.065^	-0.804 (0.435)	0.065^
Months (log transformed)	0.023 (0.223)	0.917	0.023 (0.223)	0.917
Count part (truncated negative binomial with log link)				
	$\hat{\beta}$ (Std.Error)	p-value	$\hat{\beta}$ (Std.Error)	p-value
Group: ADLIFE	0.551 (0.348)	0.113	0.551 (0.348)	0.113
Months (log transformed)	0.635 (0.266)	0.017*	0.635 (0.266)	0.017*
Oxygen	0.817 (0.364)	0.025*	0.817 (0.364)	0.025*
Charlson index	0.200 (0.077)	0.009*	0.200 (0.077)	0.009*
Metrics for model comparison				
AIC	706.406		704.406	
logLik	-339.203		-339.203	
MODEL 2	**With UHCW (N=370)**		**Without UHCW (N=346)**	
Zero hurdle part (binomial with logit link)				
	$\hat{\alpha}$ (Std.Error)	p-value	$\hat{\alpha}$ (Std.Error)	p-value
Group: ADLIFE	-1.202 (0.374)	0.001*	-1.202 (0.374)	0.001*
Site[a]:				
Osakidetza	-1.006 (0.631)	0.111	-1.006 (0.631)	0.111
UHCW	17.993 (1840.038)	0.992	NA	NA
OUH	-1.794 (0.412)	<0.001*	-1.794 (0.412)	<0.001*
Diagnosis[b]:				
COPD	-0.967 (0.416)	0.020*	-0.967 (0.416)	0.020*
COPD&HF	-0.853 (0.452)	0.059^	-0.853 (0.452)	0.059^
Months (log transformed)	0.129 (0.222)	0.560	0.129 (0.222)	0.560
Group x Site:				
ADLIFE x Osakidetza	-0.276 (0.844)	0.744	-0.276 (0.844)	0.744
ADLIFE x UHCW	1.290 (2606.941)	1	NA	NA
ADLIFE x OUH	1.855 (0.536)	0.001*	1.855 (0.536)	0.001*
Count part (truncated negative binomial with log link)				
	$\hat{\beta}$ (Std.Error)	p-value	$\hat{\beta}$ (Std.Error)	p-value

Group: ADLIFE	0.551 (0.348)	0.113	0.551 (0.348)	0.113
Months (log transformed)	0.635 (0.266)	0.017*	0.635 (0.266)	0.017*
Oxygen	0.817 (0.364)	0.025*	0.817 (0.364)	0.025*
Charlson index	0.2 (0.077)	0.009*	0.2 (0.077)	0.009*
Metrics for model comparison				
AIC	698.329		694.329	
logLik	-332.164		-332.164	

Model 1 considers global effects for intervention and site and Model 2 considers interaction between intervention and site; [a]AMCA as reference; [b]CHF as reference; [c]No ER visit observed at UHCW during intervention period for ADLIFE nor control group; *p-value <0.05; ^p-value <0.1; Follow-up measured as month; OUH: Odense University Hospital; UHCW: University Hospitals Coventry & Warwickshire NHS Trust; ER: Emergency Room; COPD: Chronic Obstructive Pulmonary Disease; CHF: Chronic Heart Failure; NA: non-applicable.

CONSORT 2025 checklist of information to include when reporting a randomised trial*

Section / Topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	Page 1 (Title)
	1b	Structured summary of the trial design, methods, results, and conclusions	Page 2 (Abstract)
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Page 2&6 (Abstract, Study design)
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	Page 5 (Ref 11)
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	Pages 7&16 (Data collection, Data availability, Code availability)
Funding and conflicts of interest	5a	Sources of funding and other support (e.g., supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	Page 16 (Acknowledgements)
	5b	Financial and other conflicts of interest of the manuscript authors	Page 17 (Competing interests)
Introduction			
Background and rationale	6	Scientific background and rationale	Page 4 (Introduction)

Objectives	7	Specific objectives related to benefits and harms	Page 5 (Introduction)
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	Page 7(Study design)
Trial design	9	Description of trial design including type of trial (e.g., parallel group, crossover), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory)	Page 5 (Study design)
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	Page 5 (Study design)
Trial setting	11	Settings (e.g., community, hospital) and locations (e.g., countries, sites) where the trial was conducted	Page 5 (Study design)
Eligibility criteria	12a	Eligibility criteria for participants	Page 5 (Study design)
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., surgeons, physiotherapists)	NA
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed	Page 7 (The ADLIFE intervention and the Standard of Care)
Outcomes	14	Pre-specified primary and secondary outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome	Pages 7, 8, 9 (Data collection and Analysis)
Harms	15	How harms were defined and assessed (e.g., systematically, non-systematically)	NA
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	Page 6 (Study design)

	16b	Explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	Pages 6 (Study design) and 8 (Analysis). Propensity score matching (PSM) used
	17b	Type of randomisation and details of any restriction (e.g., stratification, blocking and block size)	Pages 6 (Study design) and 8 (Analysis), PSM used
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (e.g., central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	Pages 6 (Study design) and 8 (Analysis), PSM used
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	Pages 6 (Study design) and 8 (Analysis), PSM used
Blinding	20a	Who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors, data analysts)	Page 6 (Study design)
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	NA
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Pages 8-10 (Analysis)
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group	Page 10 (Analysis)
	21c	How missing data were handled in the analysis	NA

	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post-hoc	Page 13
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	Page 11 (Descriptive analysis and figure S1. Flow-chart of recruitment)
	22b	For each group, losses and exclusions after randomisation, together with reasons	Table 2
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	Page 11 & Table 1 & Table 2
	23b	If relevant, why the trial ended or was stopped	NA
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (e.g., where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended [fidelity])	NA
	24b	Concomitant care received during the trial for each group	NA
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	Table 1 and Table 2
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	Pages 11, 12, 13. Results section
Harms	27	All harms or unintended events in each group	NA

Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post-hoc	Page 13 (Results)
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 13-14 (Discussion)
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	Page 13-14 (Discussion)

NA: non-applicable

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123. https://dx.doi.org/10.1136/bmj-2024-081123.