Supplementary Materials

Helping low-income smokers quit: Findings from a randomized controlled trial comparing specialized quitline services with and without social needs navigation

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Supplementary Table 1. CONSORT checklist

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6,7
	2b	Specific objectives or hypotheses	7,8
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	13,14
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	14-16
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	14,15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	16,17, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	17, Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	16,17
	14b	Why the trial ended or was stopped	13,14
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	15,16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17-19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	17-19, Figure 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	17,18
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21,22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	21
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19,20
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3,16

Supplementary Table 2. Biochemical verification sensitivity analyses of self-reported smoking cessation at 6-month follow-up.

	Four intervention group comparison				
	Standard QL only *n=485*	**Standard QL + Navigation** *n=484*	**Specialized QL only** *n=485*	**Specialized QL + Navigation** *n=490*	**p-value**
Outcome	*Frequency (%)*				
Accepted biochemical test	64 (13·2)	40 (8·3)	63 (13·0)	58 (11·8)	·06
Completed biochemical test	20 (4·1)	9 (1·9)	14 (2·9)	15 (3·1)	·23
Cessation confirmed	9 (1·9)	6 (1·2)	6 (1·2)	4 (0·8)	·55

Supplementary Materials Section 3. Methods for imputing missing data

We imputed missing data using the Multivariate Imputation by Chained Equations (MICE) package in R (van Buuren, 2021). Our imputation dataset included baseline data, intervention-use data, and the primary cessation outcome of the study (7-day point prevalence abstinence at 6-month follow-up). All variables included in the imputation dataset are listed below.

Using the MICE package, each variable with missing data had its own imputation model. We used logistic regression to impute the primary outcome variable and all other binary variables with missing data, predictive mean matching for all continuous variables with missing data, proportional odds model imputation for all ordinal variables with missing data, and polytomous logistic regression for all nominal variables with missing data.

We initially generated a set of 20 imputed datasets to test our primary outcome analysis. We used the initial set of imputed datasets and the model results to run the howmanyimputations package in R to estimate the minimum number of imputations needed (von Hippel, 2019). Based on the recommended number of imputations from the howmanyimputations package, we generated a final set of 95 imputed datasets. We then conducted the primary outcome analysis and per protocol sensitivity analysis using the 95 imputed datasets.

References

1. van Buuren S. Multivariate Impultation by Chained Equations v. 3.13.0. 2021. Retrieved from https://cran.r-project.org/web/packages/mice/mice.pdf
2. von Hippel P. How many imputations do you need? 2019. Retrieved from https://statisticalhorizons.com/how-many-imputations

Variables in imputation dataset

- 7-day point prevalence abstinence at 6-month follow-up
- 7-day point prevalence abstinence at 3-month follow-up
- Count of quitline calls
- NRT sent by quitline
- Count of navigation calls
- Gender
- Age
- Race
- Ethnicity
- Income
- Education
- Children ≤ 18
- Home smoking ban
- Count of unmet social needs
- PHQ-2 score
- Perceived stress score
- Mean social support
- Insurance status
- Age started tobacco
- Heaviness of smoking

- Use cigars
- Use cigarillos
- Use pipe
- Use smokeless tobacco
- Use e-cigs
- Bought cigarettes for self
- Bought cigarettes for others
- Bummed cigarettes
- Smoked discarded cigarettes
- Ever made quit attempt
- Sleep trouble
- Have personal doctor
- Self-rated health
- Hx of asthma
- Hx of ADHD
- Hx of Bipolar
- Hx of CAD or Heart Disease
- Hx of COPD
- Hx of Cancer
- Hx of Depression
- Hx of Drug or alcohol use disorder
- Hx of Anxiety
- Hx of PTSD
- Hx of Schizophrenia
- Hx of DiabetesTP1
- Hx of DiabetesTP2
- Employment status
- Study group