Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation: randomized controlled non-clinical trial

DOCUMENT: SAR-2024-003-IJ-v01

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2024-02-05

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Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation: randomized controlled non-clinical trial

Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- CI: confidence interval
- SD: standard deviation

2 CONTEXT

2.1 Objectives

To determine the efficacy of a novel medical device for aiding in ultrasound-guided intravenous cannulation procedures.

3 METHODS

The data procedures, design and analysis methods used in this report are fully described in the annex document **SAP-2024-003-IJ-v02**.

This analysis was performed using statistical software R version 4.3.2.

4 RESULTS

4.1 Study population and follow up

4.1.1 Study population

A total of 62 participants were recruited to the trial. Of those, 63% were female and the average age was 24 years (Table 1, see also Figure A1 in the Appendix).

Table 1 *Characteristics of the participants in the trial.*

Characteristic	N = 62
Age (years), Mean (SD)	23.6 (6.6)
Sex, n (%)	
F	39 (63%)
M	23 (37%)
Experience (years), n (%)	
0	58 (94%)
1	1 (1.6%)
2	1 (1.6%)
5	1 (1.6%)
6	1 (1.6%)

Previous experience with the cannulation procedure ranged between 0 and 6 years but most participants (94%) lacked any prior experience with the cannulation procedure.

4.1.2 Experimental conditions

A total of 124 measurements were performed for the trial across both conditions (Table 2). Figure 1 shows the time until successful cannulation by experimental condition on a log-scale. Median time (range) for the control group was 38s (3, 719) while the test group had 14s (2, 73). One participant (24 years, M) had an extreme value in the control condition (719s, single attempt), but showed no discrepant time under the test condition (28s, single attempt). A sensitivity analysis was run to assess the impact of this outlier in the efficacy estimate (see section 8.2.4 in the appendix).

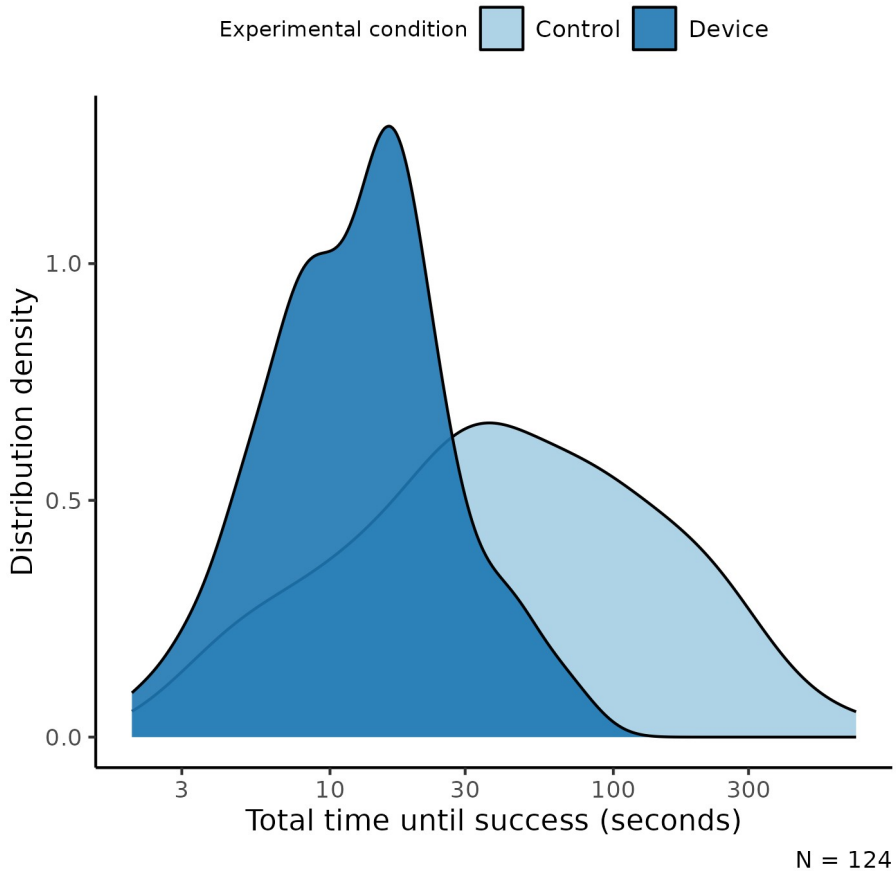

Figure 1 *Distribution of time until success, by condition, log-scale.*

Table 2 *Experimental measurements by condition.*

Characteristic	**Control**, N = 62	**Device**, N = 62
Total time until success (seconds), Median (Range)	38s (3, 719)	14s (2, 73)
Prodecure failure, n (%)	2 (3.2%)	0 (0%)
Number of attempts, n (%)		
1	21 (34%)	50 (81%)
2	21 (34%)	11 (18%)
3	7 (11%)	0 (0%)
4	7 (11%)	0 (0%)
5	4 (6.5%)	0 (0%)
6	2 (3.2%)	0 (0%)
7	0 (0%)	1 (1.6%)

The number of attempts varied across experimental conditions. It had more spread in the control condition, and was more concentrated on fewer attempts in the test condition (Table 2, Figure 2). No cannulation failures were observed in the test condition, but 2 (3.2%) were observed in the control group. Figure A2 in the Appendix indicates that most people with a higher number of attempts had no experience with the procedure.

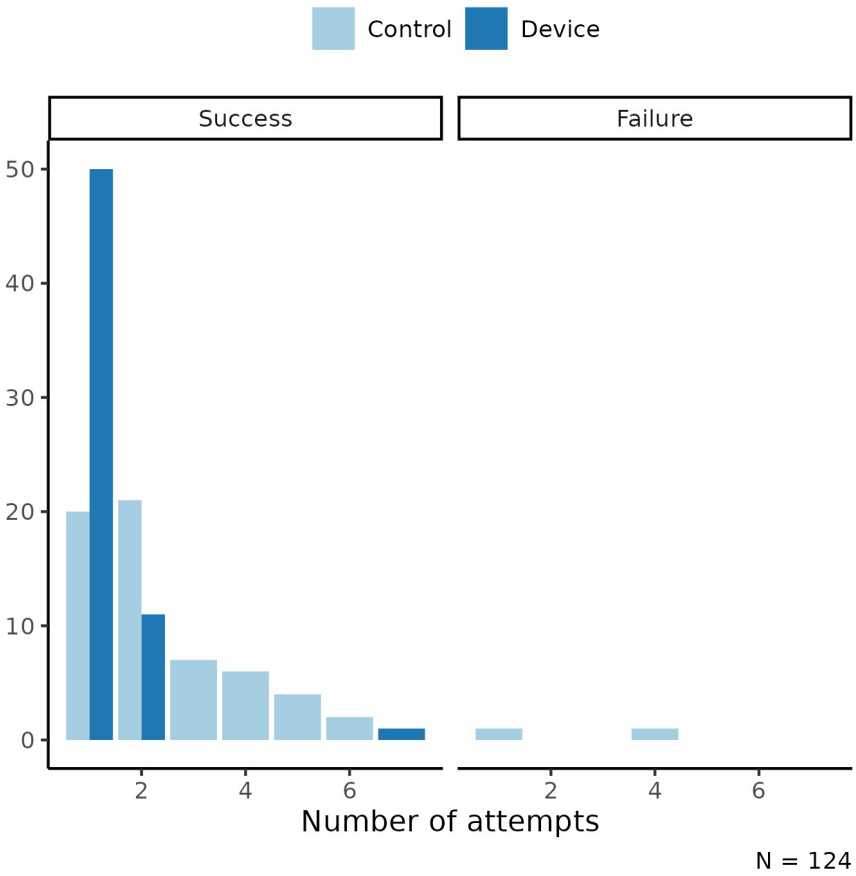

Figure 2 *Number of attempts by condition and by cannulation success.*

4.2 Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation

After removing failures to complete the cannulation procedure the analytic sample had N = 122 valid observations for the efficacy analysis. The usage of the log transformation requires the effect of the device to be interpreted as a ratio (Table 3).

The relative effect is strong, where the usage of the device reduces the time until cannulation by 46% when compared to the control condition (β = 0.54, 95% CI 0.40 to 0.73; p<0.001). In absolute terms, participants required 29.31s (95% CI [23.30, 36.89]) under the control condition and 15.96s (95% CI [12.74, 19.98]) using the device after controlling for the number of attempts (Figure 3).

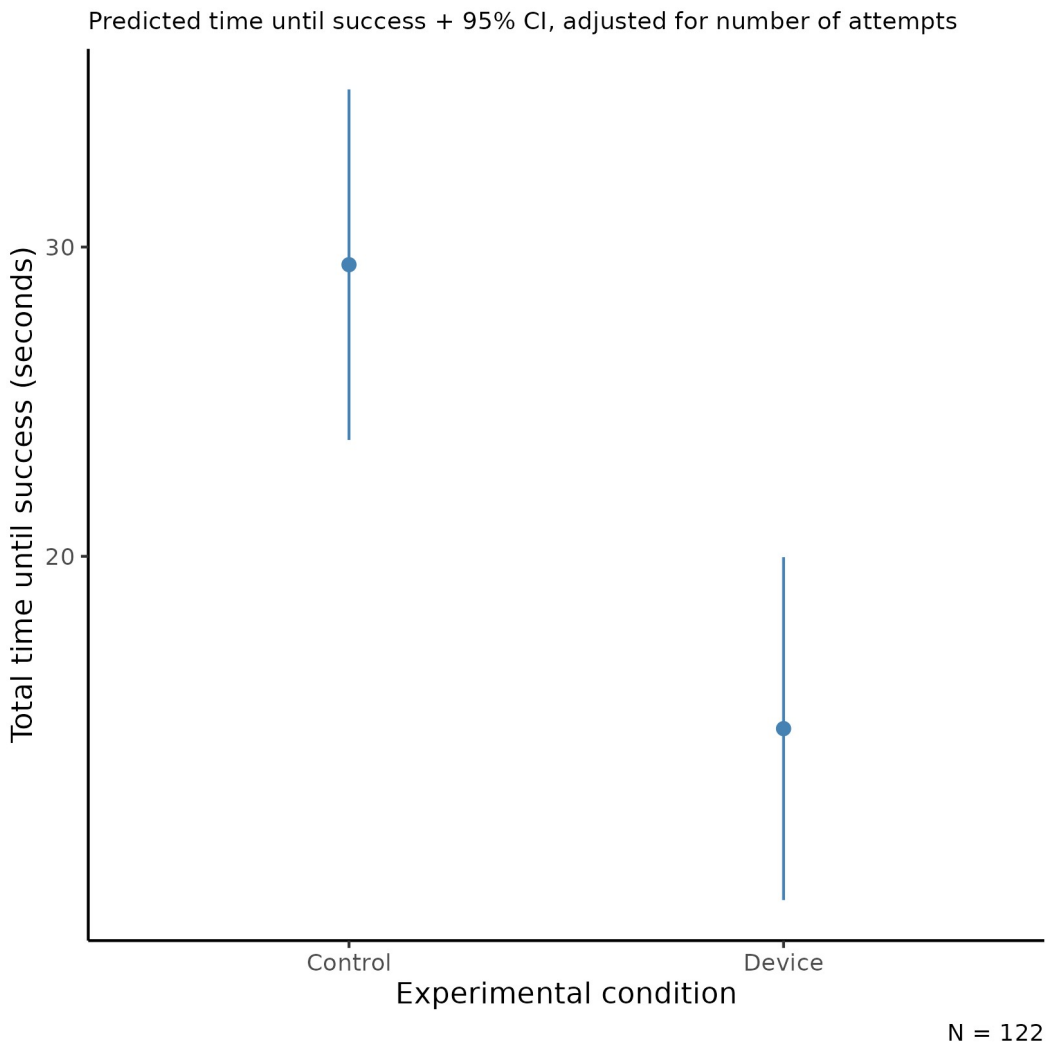

Figure 3 *Predicted time until success + 95% CI, adjusted for number of attempts.*

The number of attempts was an important predictor, with each new attempt contributing to an average increase of 62% of total time required to complete the cannulation (β = 1.62, 95% CI 1.42 to 1.85; p<0.001).

Table 3 *Effect of the device in the time of cannulation.*

Characteristic	Beta[1]	95% CI[2]	p-value
Experimental condition			
Control	—	—	
Device	0.54	0.40 to 0.73	**<0.001**
Number of attempts	1.62	1.42 to 1.85	**<0.001**

[1]Adjusted for number of attempts

[2]CI = Confidence Interval

5 OBSERVATIONS AND LIMITATIONS

Independence of observations

To assess the impact of prior experience in performing the cannulation it is important that all participants are subject to the same experimental conditions. One way of ensuring this is to standardize the procedure in the Study Protocol, so everyone that performs it does so following the same steps. Whether this includes a warm up session or practice runs before the actual measurement, everyone should be exposed to the same instructions and proceed according to the protocol. This way time will be comparable between subjects and experience will modulate the length of the procedure.

Recommended reporting guideline

The adoption of the EQUATOR network (http://www.equator-network.org/) reporting guidelines have seen increasing adoption by scientific journals. All clinical trials are recommended to be reported following the CONSORT guideline (Schulz K F, Altman D G, Moher D., 2010).

6 CONCLUSIONS

The medical device under investigation has shown efficacy in reducing the total time required for the cannulation by 46%. Participants took 15.96s when using the device and 29.31s when performing the unaided procedure.

7 REFERENCES

- **SAP-2023-019-IJ-v02** – Analytical Plan for Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation: randomized controlled non-clinical trial
- **SAR-2023-020-IJ-v01** – Data collection instrument for Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation: randomized controlled non-clinical trial
- Schulz K F, Altman D G, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials BMJ 2010; 340 :c332 (https://doi.org/10.1136/bmj.c332).

8 APPENDIX

8.1 Exploratory data analysis

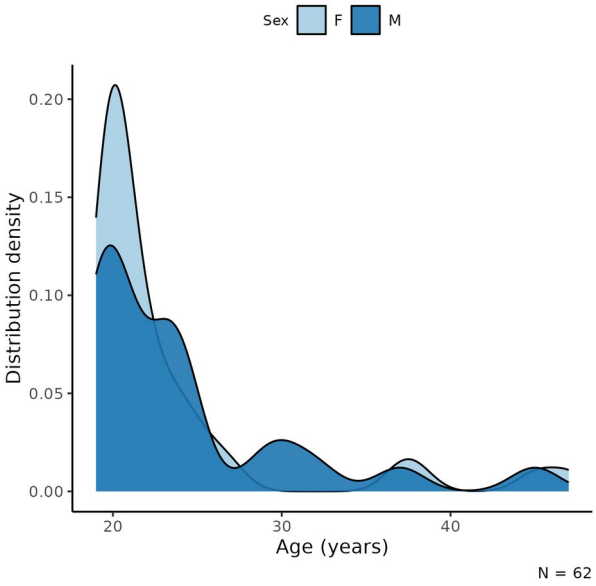

Figure A1 *Distribution of age in the study population.*

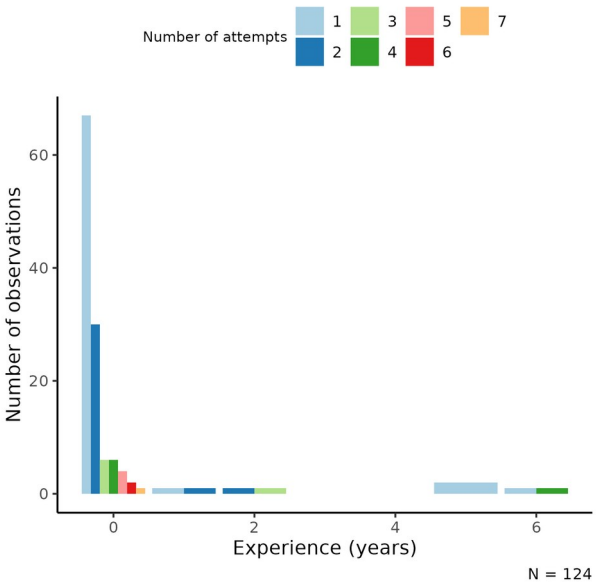

Figure A2 *caption*

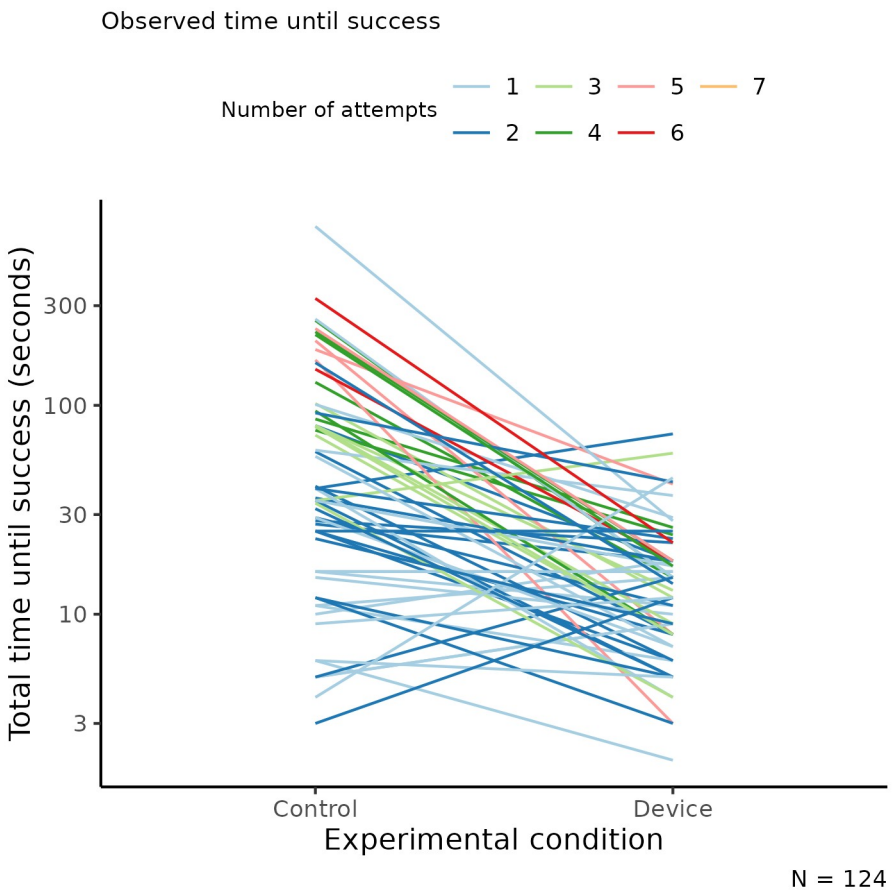

Figure A3 *caption*

8.2 Modeling strategy

- log-time

8.2.1 Evidence of interactions

- not enough data to calculate lines by experience (single participants, table 1)
- non-parallel lines in single-level regression by attempts (fig A4)

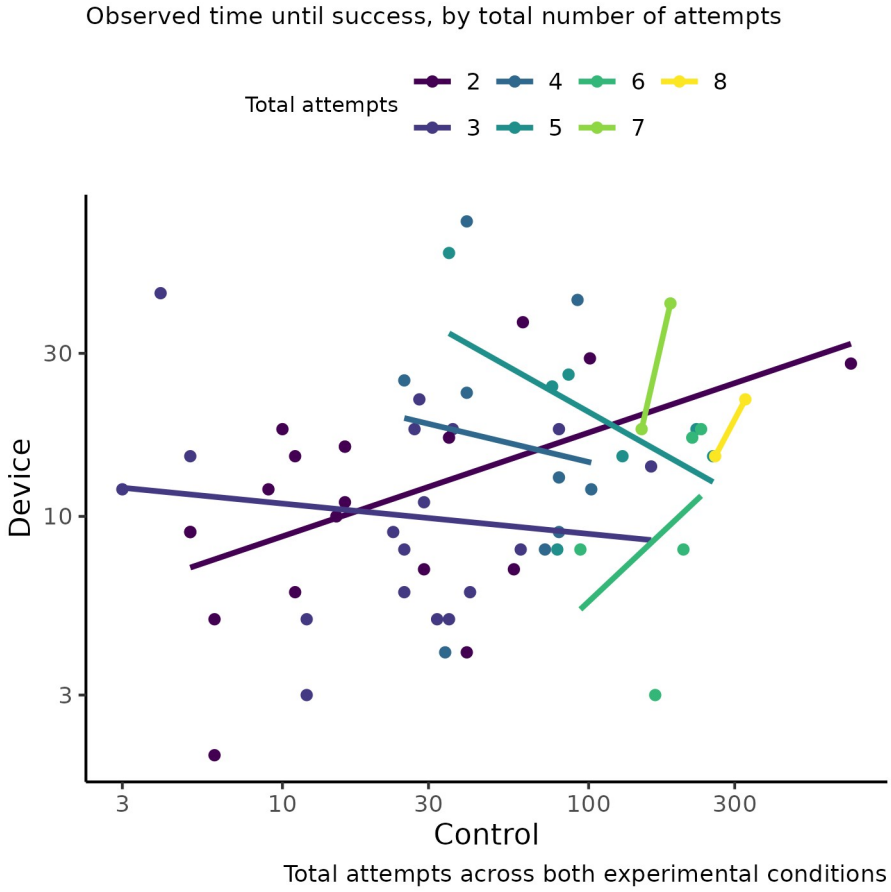

Figure A4 *caption*

8.2.2 Evaluation of candidate models

Table A1 *caption*

	Crude estimate			Adjusted estimate			Interaction with experience			Interaction with attempts		
Characteristic	**Beta**	**95% CI[1]**	**p-value**	**Beta**	**95% CI[1]**	**p-value**	**Beta**	**95% CI[1]**	**p-value**	**Beta**	**95% CI[1]**	**p-value**
(Intercept)	38.3	29.6 to 49.6	**<0.001**	12.3	8.39 to 18.1	**<0.001**	12.3	8.40 to 18.1	**<0.001**	10.2	6.74 to 15.3	**<0.001**
Experimental condition												
Control	—	—		—	—		—	—		—	—	
Device	0.32	0.24 to 0.45	**<0.001**	0.54	0.40 to 0.73	**<0.001**	0.54	0.40 to 0.74	**<0.001**	0.91	0.53 to 1.55	0.732
Number of attempts				1.62	1.42 to 1.86	**<0.001**	1.62	1.42 to 1.86	**<0.001**	1.77	1.52 to 2.06	**<0.001**
Experience (years)				1.00	0.84 to 1.19	0.967	0.99	0.80 to 1.23	0.939	1.00	0.84 to 1.18	0.962
Experimental condition * Experience (years)												
Device * Experience (years)							1.02	0.79 to 1.33	0.857			
Experimental condition * Number of attempts												
Device * Number of attempts										0.71	0.53 to 0.95	**0.022**

[1]CI = Confidence Interval

- adjusted model is better than crude estimate (tab A2)
- goodness of fit is similar between adj and final (Fig A5)
    - experience does not improve predictions (indistinguishable from adj)

Table A2 *caption*

model	npar	AIC	BIC	logLik	deviance	Chisq	Df	Pr(>Chisq)
mod.crude	4	351.0624	362.2784	-171.5312	343.0624	NA	NA	NA
mod.final	5	308.9993	323.0194	-149.4997	298.9993	44.063021275	1	<0.001
mod.adj	6	310.9975	327.8217	-149.4988	298.9975	0.001789596	1	>0.9
mod.int.experience	7	312.9633	332.5914	-149.4816	298.9633	0.034285064	1	0.9
mod.int.tries	7	307.5621	327.1902	-146.7810	293.5621	5.401200487	0	NA

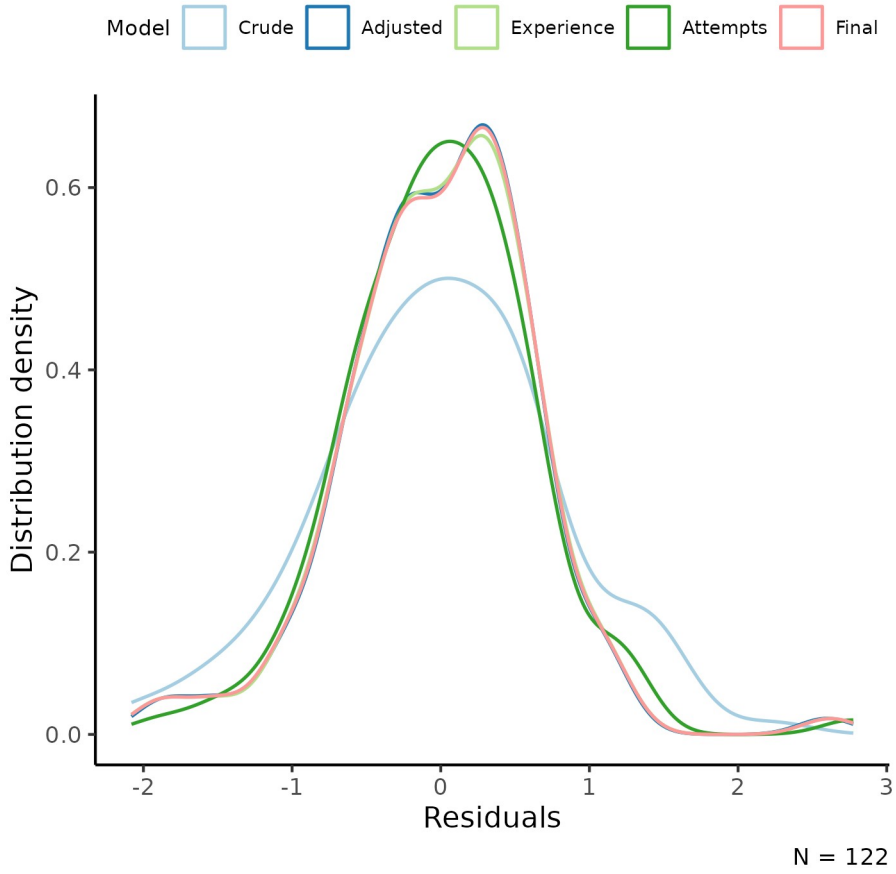

Figure A5 *caption*

8.2.3 Final model

- interaction with attempts does not significantly improve prediction (tab A3)
- final model is exposure + tries
- suggestion: ok to only report final model in manuscript, report others in supplemental material, if required by reviewers
- participant performance, smoothed version of fig A3

Table A3 *caption*

model	npar	AIC	BIC	logLik	deviance	Chisq	Df	Pr(>Chisq)
mod.final	5	308.9993	323.0194	-149.4997	298.9993	NA	NA	NA
mod.int.tries	7	307.5621	327.1902	-146.7810	293.5621	5.437275	2	0.066

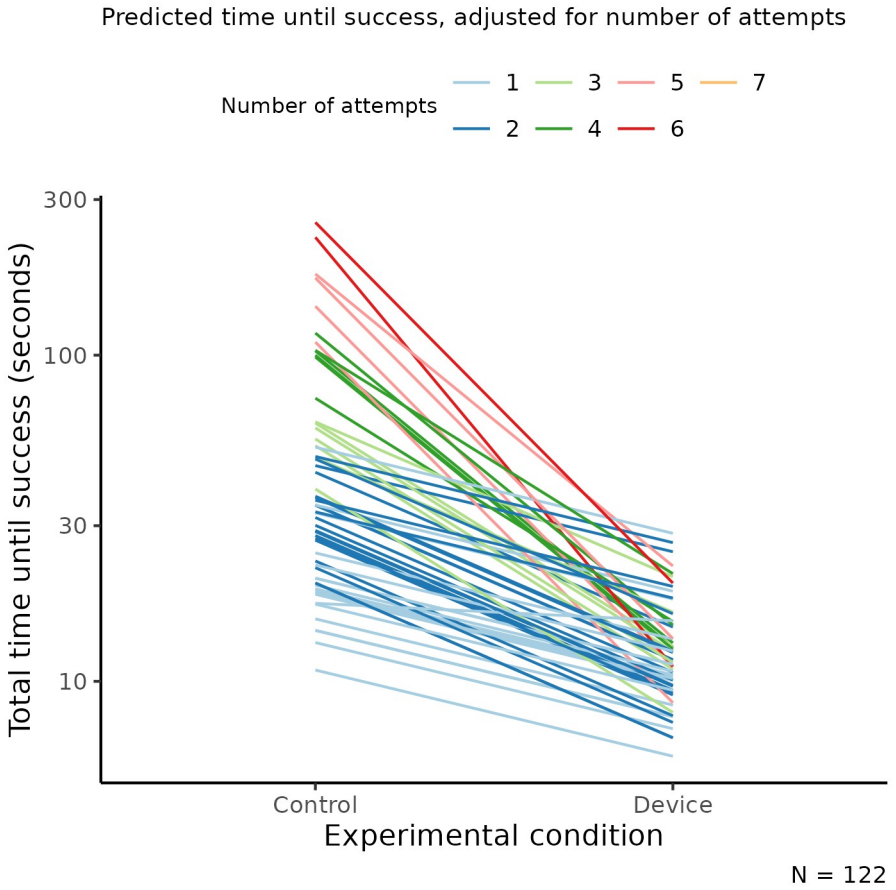

Figure A6 *caption*

8.2.4 Sensitivity to outlier

- results: small changes to estimates, no changes to conclusions (tab A4)
- conclusion: keep full data

Table A4 *caption*

	Full data			Outlier removed		
Characteristic	**Beta**	**95% CI**[1]	**p-value**	**Beta**	**95% CI**[1]	**p-value**
(Intercept)	12.3	8.44 to 18.0	**<0.001**	10.8	7.58 to 15.5	**<0.001**
exposure						
Control	—	—		—	—	
Device	0.54	0.40 to 0.73	**<0.001**	0.59	0.44 to 0.78	**<0.001**
Number of attempts	1.62	1.42 to 1.85	**<0.001**	1.67	1.48 to 1.89	**<0.001**

[1]CI = Confidence Interval

8.3 Associated analyses

This document is part of a larger project and is supported by other analyses, linked below.

Analytical Plan for Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation: randomized controlled non-clinical trial

https://philsf-biostat.github.io/SAR-2023-019-IJ/

Data collection instrument for Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation: randomized controlled non-clinical trial

https://philsf-biostat.github.io/SAR-2023-020-IJ/

8.4 Availability

All documents from this consultation were included in the consultant's Portfolio.

The portfolio is available at:

https://philsf-biostat.github.io/SAR-2024-003-IJ/

8.5 Analytical dataset

Table A5 shows the structure of the analytical dataset.

Table A5 *Analytical dataset structure*

id	exposure	outcome	sex	experience	age	censor	tries
1							
2							
3							
…							
N							

Due to confidentiality the data-set used in this analysis cannot be shared online in the public version of this report.