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Randomized Controlled ‘study-within-a-trial’ to evaluate plain language informed consent key information

Authors: Sabrina Kurtz-Rossi, Ning Smith, Nicholas Moustakas, Andreas Klein
Contributors: Noe Duenas, Svetlana Rojevsky, Benjamin Sweigart

Background: Research informed consent forms must begin with a short key information section to support participant understanding and informed decision making. But does it work? We proposed a 'study-within-a-trial’ (SWAT) to find out.

Research Question: Does key information rated “easy to read” by the Readability, Understandability, and Actionability of Key Information (RUAKI) Checklist improve participant understanding and reduce decisional conflict? And is the SWAT methodology feasible? We conducted a pilot study to find out.

Methods: The study was embedded within an actively recruiting clinical trial. Participants randomized to the intervention group received standard key information, plus an easy-to-read version. Participants in the control group received standard key information alone. After making their informed consent decision, participants received the SWAT survey.

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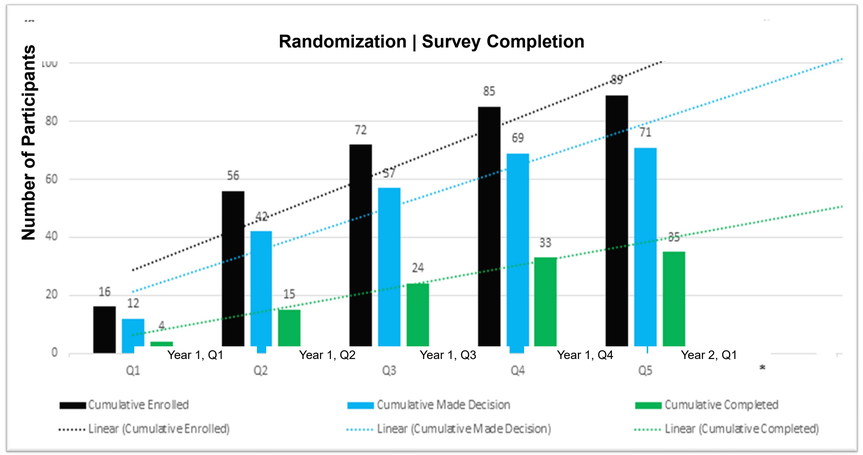
Results:

- Forty-four participants were randomized to the intervention group and 45 to the control group.
- Seventy-one participants made an informed consent decision and received the SWAT survey.
- Thirty-five completed and returned the survey.
- As this was a small pilot, significant differences between groups could not be detected.

Conclusions:

- A randomized controlled SWAT testing plain language key information on understanding and decisional conflict is feasible but will require a large-scale clinical trial.
- Based on feedback from a stakeholder advisory group, we plan on strengthening the intervention with plain language speaking as part of the consent conversation before moving forward with a fully powered study.



Among those recruited by the Parent study (N=89)	
Variable	N (%)
Met inclusion criteria (age ≥ 18 AND able to speak English)	
Yes	89/89 (100)
No	0/89 (0.0)
Randomization	
Intervention	44/89 (49.4)
Control	45/89 (50.6)
Made informed consent decision and received survey	
Yes	71/89 (79.7)
No	18/89 (20.3)

Rate of enrollment

Among those who received the SWAT survey (N=71)	
Variable	N (%)
Completed survey	
Yes	35/71 (39.3)
No	36/71 (60.7)
Among those who completed survey (N=35)	
Enrolled in parent study	
Yes	22/35 (62.9)
No	13/35 (37.1)
Among those who did not complete survey (N=36)	
Enrolled in parent study	
Yes	21/36 (58.3)
No	15/36 (41.6)

Rate of survey return

True/False Survey questions measuring understandability (N=35)		
	Intervention N=14	Control N=21
Was the purpose of the study to test the effectiveness of a new treatment?		
Correct	9 (64.3)	13 (64.9)
Incorrect	5 (35.7)	8 (38.1)
P-value	>0.99	
Was one benefits or reason to join the study that it will improve your health?		
Correct	2 (14.3)	1 (4.8)
Incorrect	12 (85.7)	20 (95.2)
P-value	>.55	
Was one of the risks or reasons not to join the study that there may be side effects?		
Correct	7 (50.0)	5 (23.8)
Incorrect	7 (50.0)	16 (76.2)
P-value	>0.15	

Preliminary findings