CALMA m-health app as an adjunct to therapy to reduce suicidal and non-suicidal self-injurious behaviors.

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DISCLOSURES

FMD, DR and RO are the owners of CALMA license.

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Background

- •Mobile app development could help people at risk of suicide and provide resources to deliver evidence-based interventions.
- •Our group developed CALMA, the first interactive mobile application in Spanish, which provides DBT-based tools to manage a suicidal crisis with the aim of preventing suicide in adolescentsand young adults.



Desarrollo de CALMA: una aplicación para dispositivos móviles inteligentes para la prevención del suicidio en adolescentes y jóvenes



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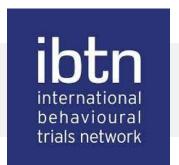
CALMA, a Mobile Health Application, as an Accessory to Therapy for Reduction of Suicidal and Non-Suicidal Self-Injured Behaviors: A Pilot Cluster Randomized Controlled Trial

Demián E. Rodante (D), Marcela I. Kaplan, Ramiro Olivera Fedi, Pablo Gagliesi, Agustina Pascali, Paula S. José Quintero, Emilio J. Compte, Ana I. Perez, Melina Weinstein, Luciana C. Chiapella, and Federico M. Daray (D)



Previous study: Cluster Pilot RCT in adults

- •CALMA showed a high probability of decreased in suicidal ideation, suicidal plan, suicidal gesture, thoughts about NSSI and NSSI pre- and post-intervention;
- •High probability of a greater decrease in suicidal ideation and suicidal gesture before and after the intervention for the group that received CALMA compared to the comparison group,





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A randomized 3-month, parallel-group, controlled trial of CALMA m-health app as an adjunct to therapy to reduce suicidal and non-suicidal self-injurious behaviors in adolescents: study protocol

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CALMA, a DBT-based m-health app as a complement to therapy for the reduction of suicidal and non-suicidal self-injurious behaviors in adolescents treated in public hospitals in Argentina: preliminary results.





•To test the effectiveness, safety and level of engagement of the CALMA app in adolescents aged 10 to 18 who are treated in mental health services of two public hospitals (but no DBT), we are conducting a parallel-group, two-arm randomized controlled trial (ClinicalTrials.gov NCT05453370).

METHOD

Participants are being assessed face-to-face and via video call at four timepoints: day-0 (baseline), day-30, day-60, and day-90. A total of 29 participants per group will be included.

Change in the frequency of suicidal and NSSI behaviors will be compared between groups (SITBI) as well as the level of emotional dysregulation, level of app engagement and time of psychiatric admission during the follow-up period (30-day, 60-day, 90-day).

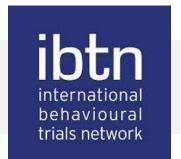


Figure 1. Participant Flow Chart.

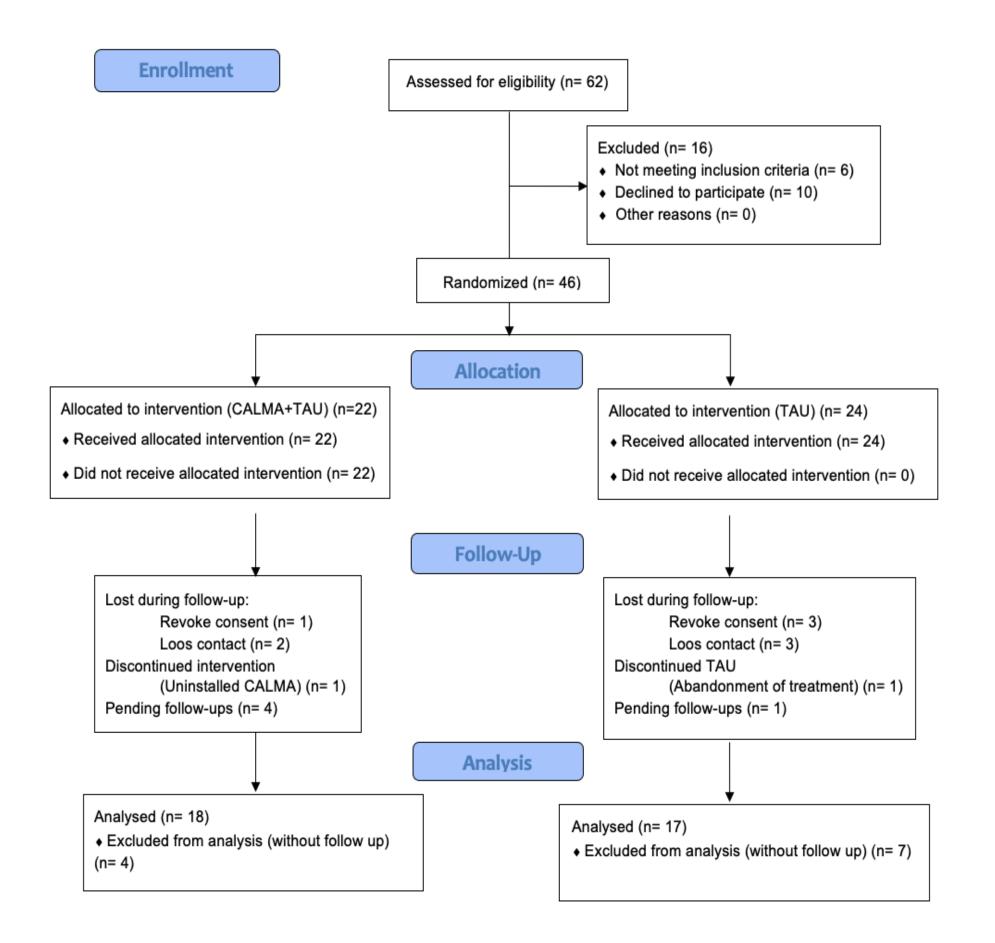




Figure 2. Distribution of patients according to index event.

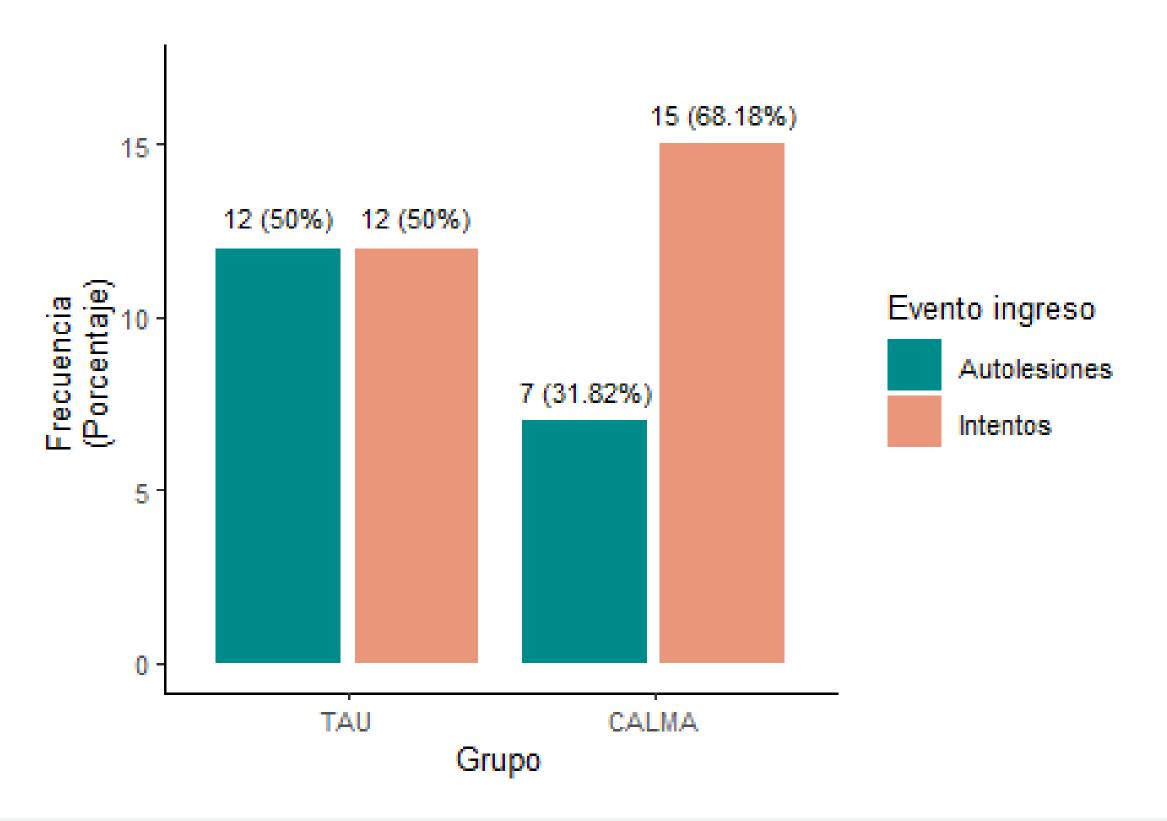




Table 1. Relative percentage differences in index behavior according to follow-up time

Variables	TAU	CALMA	р
First follow-up, n (%)	17 (48.6)	18 (51.4)	
Frequency change in NSSI, median (Q1-Q3)	-70.0 (-95.0, 25.0)	-25.00 (-50.0, 100.0)	0.460
Frequency change in suicide attempts, median (Q1-Q3)	-100.0 (-100.0, -100.0)	-100.0 (-100.0, -100.0)	0.585
Frequency change in index event, median (Q1-Q3)	-100.0 (-100.0, 0.0)	-100.0 (-100.0, -58.3)	0.456
Frequency chance in suicidal ideation, median (Q1-Q3)	-83.33 (-100.0; -59.17)	-100.0 (-100.0, 0.00)	0.918
Frequency chance in Thoughts about NSSI	-90.0 (-96.7; -57.5)	-80.0 (-100.0, -66.7)	0.863
Second follow-up, n (%)	15 (53.6)	13 (46.4)	
Frequency change in NSSI, median (Q1-Q3)	-68.3 (-97.5, 125.0)	17.5 (-42.5, 106.3)	0.355
Frequency change in suicide attempts, median (Q1-Q3)	-100.0 (-100.0, -100.0)	-100.0 (-100.0, -100.0)	0.456
Frequency change in index event, median (Q1-Q3)	-100.0 (-100.0, -25.0)	-100.0 (-100.0, -40.0)	0.702
Frequency chance in suicidal ideation, median (Q1-Q3)	-40.0 (-100.0, 0.0)	-100.0 (-100.0, -58.33)	0.173
Frequency chance in Thoughts about NSSI	-80.0 (-100.0, -50.0)	-77.5 (-90.0, -56.25)	0.614
Third follow-up, n (%)	14 (58.3)	10 (41.7)	
Frequency change in NSSI, median (Q1-Q3)	-86.7 (-100.0, 25.0)	25.0 (-37.5, 87.5)	0.521
Frequency change in suicide attempts, median (Q1-Q3)	-100.0 (-100.0, -100.0)	-100.0 (-100.0, -100.0)	0.280
Frequency change in index event, median (Q1-Q3)	-100.0 (-100.0, -18.3)	-100.0 (-100.0, -100.0)	0.512
Frequency chance in suicidal ideation, median (Q1-Q3)	-95.8 (-100.0, -19.2)	-100.0 (-100.0, -100.0)	0.143
Frequency chance in Thoughts about NSSI	-85.0 (-100.0, -76.7)	-85.0 (-95.0, -68.8)	0.694



Figure 3. Survival curves according to treatment.

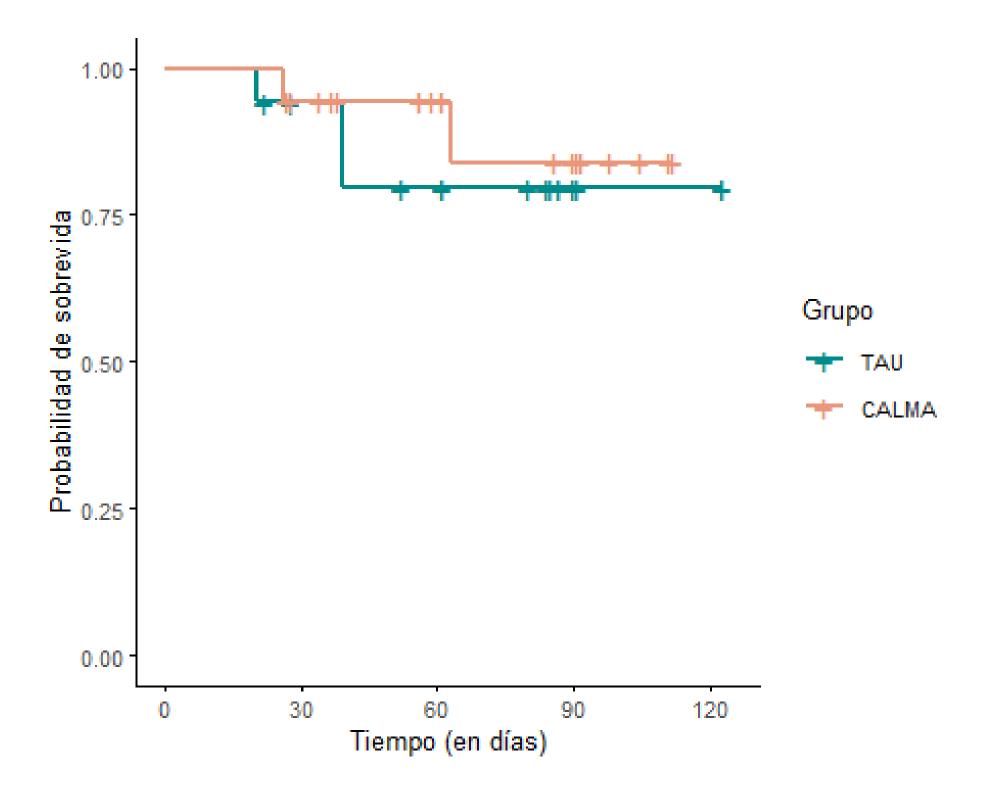
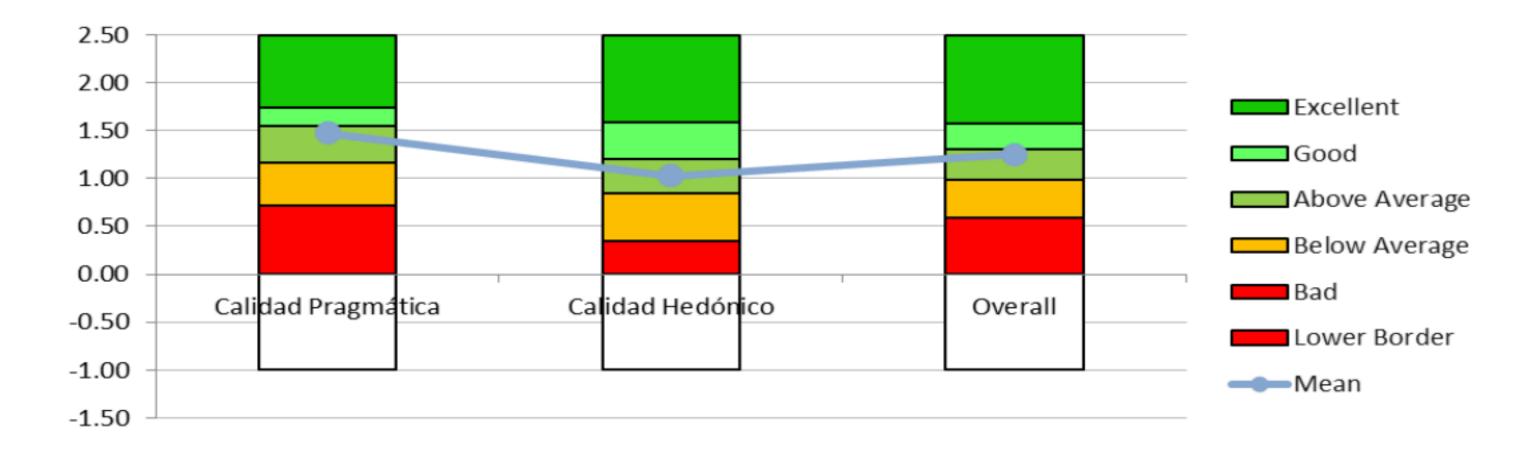




Figure 4. CALMA usability assessment (s-UEQ).





DISCUSSION

- At the time of the preliminary analysis, both groups have not differed in main outcomes; an effect of greater magnitude although not significant is observed on suicidal ideation, as we have seen in our pilot study (Rodante et al, 2020). CALMA shows good acceptability.
- Possible explanations for the low effectiveness of CALMA: lower recruitment rate, lost in follow-up (30%), the low number of events during follow-up and the reduced levels of use of the application (66%), TAU characteristics.
- The RCT is still in the recruitment stage (target: 29 per group).



Future directions

- Regardless of the final results, the next RCT will focus again on adolescents but who are in a DBT-A program.
- Improvement of CALMA functions and tools (security plan, gamification, new cards and skills).
- Ecological momentary assessment (EMA).
- User experience (focus groups).
- Version adapted to the needs of the treating mental health team.



Thanks

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