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RECRUITMENT AND PARTICIPANT FOLLOW-UP STRATEGIES: DATA FROM A RANDOMIZED CONTROLLED TRIAL CONDUCTED VIA REDCAP

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Background: Conducting randomized controlled trials (RCTs) using digital technologies is potentially an accessible, low cost and strategic approach to investigate interventions to improve the beliefs of consumers with regard to low back pain (LBP). However, there are challenges with this research approach, considering that Brazil is a large populous country, and restricted funding scenarios present difficulties for recruitment and follow-up in digital RCTs.

Objectives: To describe the recruitment process and recruitment rates, as well as follow-up rates during an RCT using digital recruitment and follow-up strategies.

Methods: This observational study is secondary to the RCT registered in The Brazilian Registry of Clinical Trials (RBR-10kpgx78). We invited Brazilian residents to tell us what they think about LBP and recorded their responses in Research Electronic Data Capture (REDCap). Until March 15th, 2023, we used three digital recruitment strategies: 1) posts on social networks; 2) paid traffic; 3) WhatsApp® messages. We collected outcomes at immediate and eight-week follow-up after exposure to health education materials. The immediate follow-up must be answered soon after the exposure, otherwise, we send return reminders by: 1) e-mail integrated into REDCap; 2) WhatsApp®; 3) social networks; 4) e-mail of the responsible researcher; daily for the immediate follow-up and every three days for the eight-week follow-up. In this study, we describe the strategies and recruitment rate (randomized people in relation to those who started the survey); response rates (proportion of those who responded to the follow-up in relation to those randomized eligible for that stage).

Results: Recruitment started on December 16th, 2022, and we considered data from 170 adult participants. We posted 32 publications on social media profiles. We invested R\$142,35 in two 7-day paid traffic campaigns, reaching 26,203 accounts, click-through rate of 2.19% and conversion rate of 2.78%. We sent WhatsApp® messages in bulk on two specific days: 1) 19/12/22, with 60 new recruits in one week; 2) 31/01/23, with 65 new recruits at the same time. In three months, we have 205 respondents to the invitation and 170 randomized, indicating a recruitment rate of 82.9%. The response rates for the immediate and eight-week follow-up are 81.2% and 28.3%, respectively, and the median response times are 6.1 and 64.9 days, in that order. Immediate follow-up was completed right away by 39.9% of the participants and the return via WhatsApp® reminders represented 46.4%. At the eight-week follow-up, e-mails integrated into REDCap accounted for 57.7% of survey returns.

Conclusions: The rates show the viability of combined recruitment strategies on social networks and WhatsApp®. The retention of respondents during the RCT can be maintained through WhatsApp® messages and e-mails integrated into REDCap.

Implications: Designing an electronically conducted RCT needs a diversified strategic plan for recruiting and retaining participants,

as well as iterative monitoring of the results, in order to optimize recruitment and follow-up rates.

Keywords: Research Subject Recruitment, Follow-Up Studies, Randomized Controlled Trial

Conflict of interest: The authors declare no conflict of interest.

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PSYCHOMETRIC PROPERTIES OF THE YC-PEM BRAZIL

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Background: Participation is a critical concept for children's health and their interaction with the context in which they live. Recently, participation has been understood as a family of constructs that includes attendance (frequency of activities carried out) and involvement (engagement, persistence, social connection, affection, and personal preferences). Young children with disabilities are at risk of experiencing participation restriction, which reinforces the importance of incorporating participation assessment measures into child rehabilitation. In this sense, the Participation and Environment Measure - Young Children (YC-PEM) stands out, an instrument developed based on the model of the International Classification of Functioning, Disability and Health (ICF), centered on the perception of the caregiver, to assess the participation and environment of young children, with or without disabilities.

Objective: To establish the initial psychometric properties of the YC-PEM translated into Brazilian Portuguese.

Methods: This is a methodological study. A total of 143 Brazilian children with and without disabilities from ages 0 to 5 years and 11 months were included. Recruitment was voluntary, resulting from dissemination on social networks and partnerships with universities and teaching clinics in Brazil. The parents/guardians responded to the instrument YC-PEM. The variables analyzed were frequency of participation, involvement, and desire for change; supports, barriers, environmental helpfulness, environmental resources and overall environmental support, in the three sections: home, daycare/preschool and community, adopting a significance level of $\alpha=0.05$. The Cronbach's alpha test was used to assess internal consistency (IC). To check the construct validity, we investigated differences between groups using Mann-Whitney or Chi-square tests.

Results: 73 children with (mean age 24.6 months) and 70 children without disabilities (mean age 30.9 months) of both genders participated, among which 41% attended daycare/preschool. Cronbach's alpha ranged from 0.625 to 0.991 in the different subscales, which confirms its internal consistency. As for construct validity, the instrument could detect statistically significant differences between the groups in the domains of frequency of participation and involvement in daycare/preschool, involvement in the community, help from the environment, resources and General support from the environment in all 3 instrument sections.