

Comparison of the effectiveness of eDiary alarms on completion compliance in adult and pediatric participants in atopic dermatitis clinical trials

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INTRODUCTION

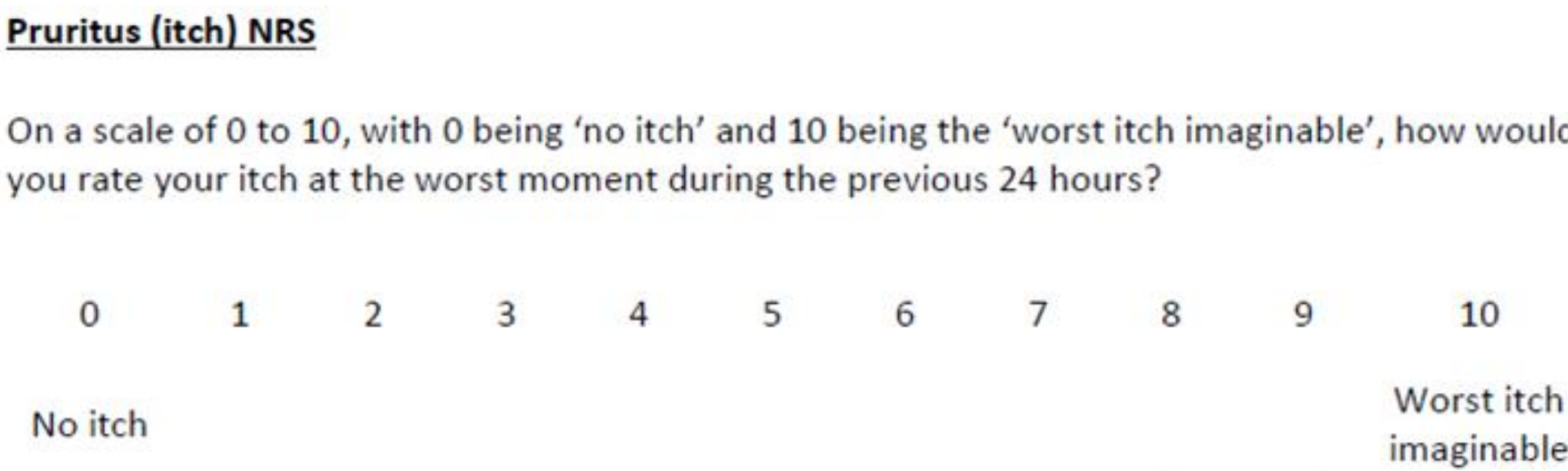
In Atopic Dermatitis (AD) clinical trials, Patient-Reported Outcome Measures (PROMs) are invaluable resources that can be used to supplement endpoint data and to determine a study medication’s effectiveness during treatment. These PROMs can be completed either at the site or at home. For example, the Peak Pruritus Numerical Rating Scale (PP-NRS) is a validated PROM tool¹ used to assess the maximum severity of pruritus, as reported by participants, between study visits through an eDiary.

To ensure timely completion of the assessment, best practice recommends implementing device alarms or reminders to enhance compliance^{2,3}. The objective of this study was to investigate the impact of device alarms on completion compliance of PP-NRS eDiaries in adult and pediatric participants.

METHODS

Over 680 000 completed PP-NRS eDiary entries were collected from adult (n=5 532) or pediatric (12-18 years old) participants (n=1 191) across 8 ongoing AD studies. The eDiaries were completed on the participants’ own devices or a provisioned device every day throughout the study period. Alarms were programmed for each eDiary reporting window, and the difference between the participants’ eDiary first set alarm time and the time the eDiary was first opened was analyzed. Only completed entries were included in this analysis.

FIGURE 1: EXAMPLE OF PP-NRS eDIARY



DISCUSSION

The observed trend in the differences between alarm time and eDiary opening time appeared similar in both age groups, suggesting both age groups exhibited similar eDiary completion time behaviors. This analysis suggests that eDiary alarms are useful in driving completion compliance for many individuals in both adult and pediatric participants, encouraging them to answer their eDiary within two-hours of their scheduled alarm time. Although this supports the use of eDiary alarms to enhance completion compliance in AD clinical trials, sites and study teams should continue to communicate the importance of eDiary completion to participants and proactively follow up with non-compliant patients throughout the trial to ensure optimal compliance and proper completion of assessments.

REFERENCES

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RESULTS

FIGURE 2: TIME DIFFERENCE BETWEEN STARTING DIARY AND THEIR ALARM

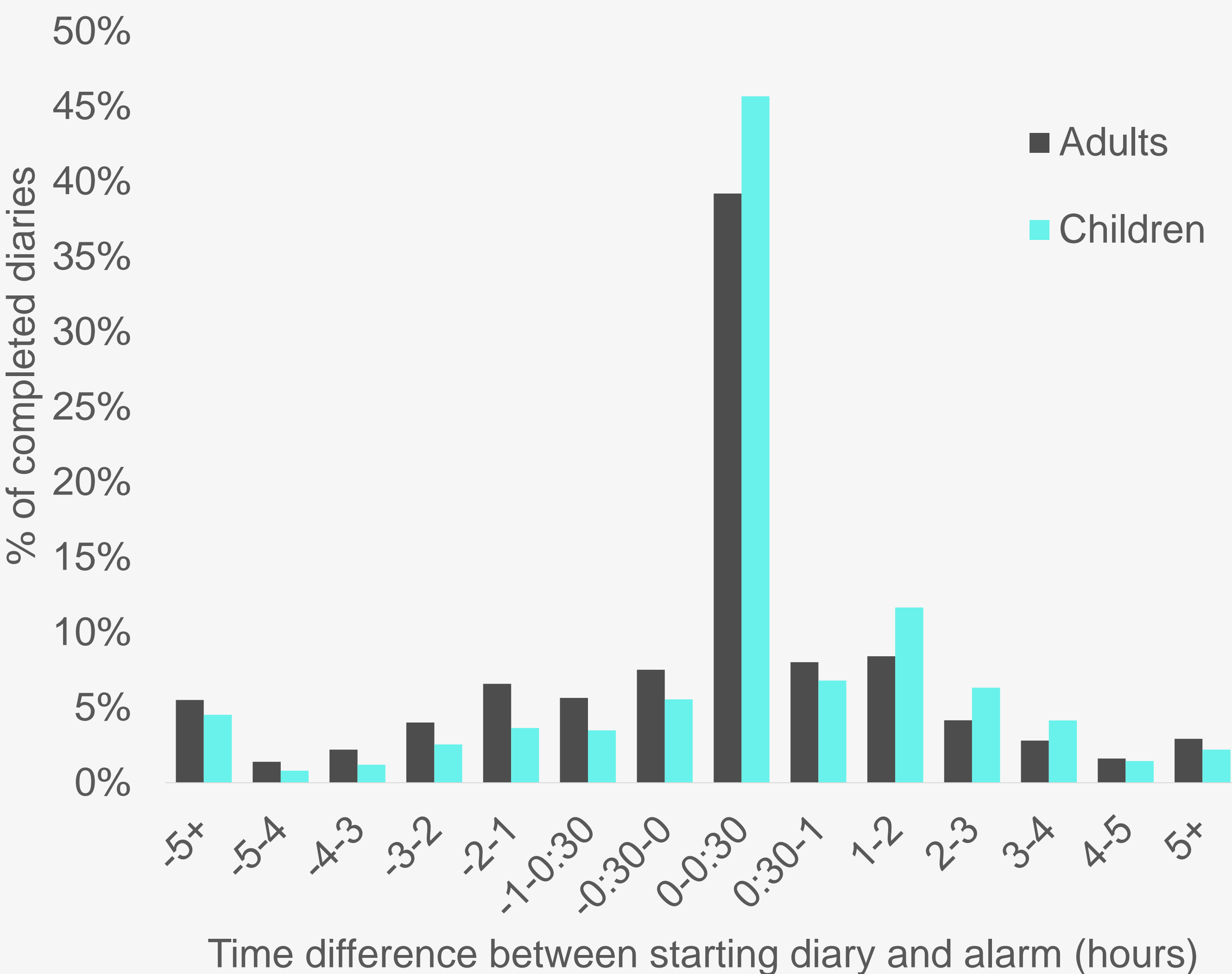


TABLE 1: TIME DIFFERENCE BETWEEN STARTING DIARY AND THEIR ALARM

Time	Adult %	Children %
-5+	6%	5%
-5-4	1%	1%
-4-3	2%	1%
-3-2	4%	3%
-2-1	7%	4%
-1-0:30	6%	3%
-0:30-0	8%	6%
0-0:30	39%	46%
0:30-1	8%	7%
1-2	8%	12%
2-3	4%	6%
3-4	3%	4%
4-5	2%	1%
5+	3%	2%

- 67% of adult eDiaries (n=448 200) and 78% (n= 106 574) of child eDiaries were opened after the scheduled alarm time
- Of these eDiaries:
 - 58% of adult eDiaries (n=261 718) and 46% (n=62 201) of child eDiaries were answered within 30 minutes of the first set alarm time
 - 83% of adults eDiaries (n=371 468) and 64% (n=87 350) of child eDiaries were answered within 2 hours of the first set alarm time