# Rapid paper

# Digital health programme improves quality of life in rheumatoid arthritis: a retrospective analysis of real-world data

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*Competing interests: the authors are employees of Sidekick Health.*

**ABSTRACT**

**Objective.** *Sidekick Health launched a 16-week digital support programme for people with rheumatoid arthritis in 2021. The objective of this retrospective analysis was to understand whether quality of life (QoL; sleep quality, energy and stress levels) improved for users engaged with the programme in a real-world setting.*

**Methods.** *This analysis included 635 users who engaged with the programme after the first week, out of 1541 who enrolled. Users self-reported QoL up to four times per week on their phones. Survival bias was investigated by comparing pre-post QoL scores of the full analysis set (all users) and the complete case set (programme completers). Users were divided into highly-engaged and less-engaged groups based on the weekly average number of in-app activities by iterative K-means clustering. Mixed models for repeated measures were used to estimate changes in QoL for highly- versus less-engaged groups.*

**Results.** *Both the full analysis set and the complete case set had significant pre-post improvements in energy and stress; this suggested that survival bias did not have a substantial effect on these real-world data. Both the highly- and less-engaged groups experienced significant longitudinal improvements in all QoL outcomes. Highly-engaged users achieved better scores in energy, stress, and sleep than less-engaged users. Moreover, a significant time-group interaction for sleep showed that highly-engaged users not only had better sleep scores, but also experienced larger improvements over time than less-engaged users.*

**Conclusion.** *These findings demonstrate that a 16-week digital support programme improves self-reported QoL measures, supporting the 2021 EULAR recommendations to incorporate digital healthcare into routine practice. Noteworthy is the study's relevance in the context of the increasing importance of patient empowerment in managing chronic diseases.*

## Introduction

Rheumatoid arthritis (RA) is a chronic autoimmune disease that causes joint pain, stiffness, and swelling. Patients experience fatigue and fibromyalgia, as well as negative effects on emotional and psychological wellbeing, and quality of life (QoL) (1-3).

The heterogeneity of RA makes it challenging to treat and manage. Periods of relative remission and high disease activity (flares) are unpredictable and can be debilitating (4). Many patients are affected by extra-articular manifestations and comorbidities: *e.g.* 50% increased cardiovascular mortality risk (5); 32–45% have metabolic syndrome (6, 7); and 30–40% respiratory diseases (5). A holistic and individualised treatment is required for this complex disease.

The gold-standard treat-to-target approach is disease-modifying but not a cure: medication and physical therapy are iterated regularly according to individual rates of progression (2). Medications have substantial side effects and poor adherence (8). Physical activity can help to preserve joint mobility and flexibility (9), while lifestyle changes such as healthy weight maintenance and smoking cessation can also help to manage symptoms and minimise extra-articular manifestations and comorbidities (10). This treatment complexity is reflected in total annual healthcare costs: US patient spend is approximately three times higher than matched non-RA controls, $20,919 *versus* $7179 (11).

Digital support programmes can help

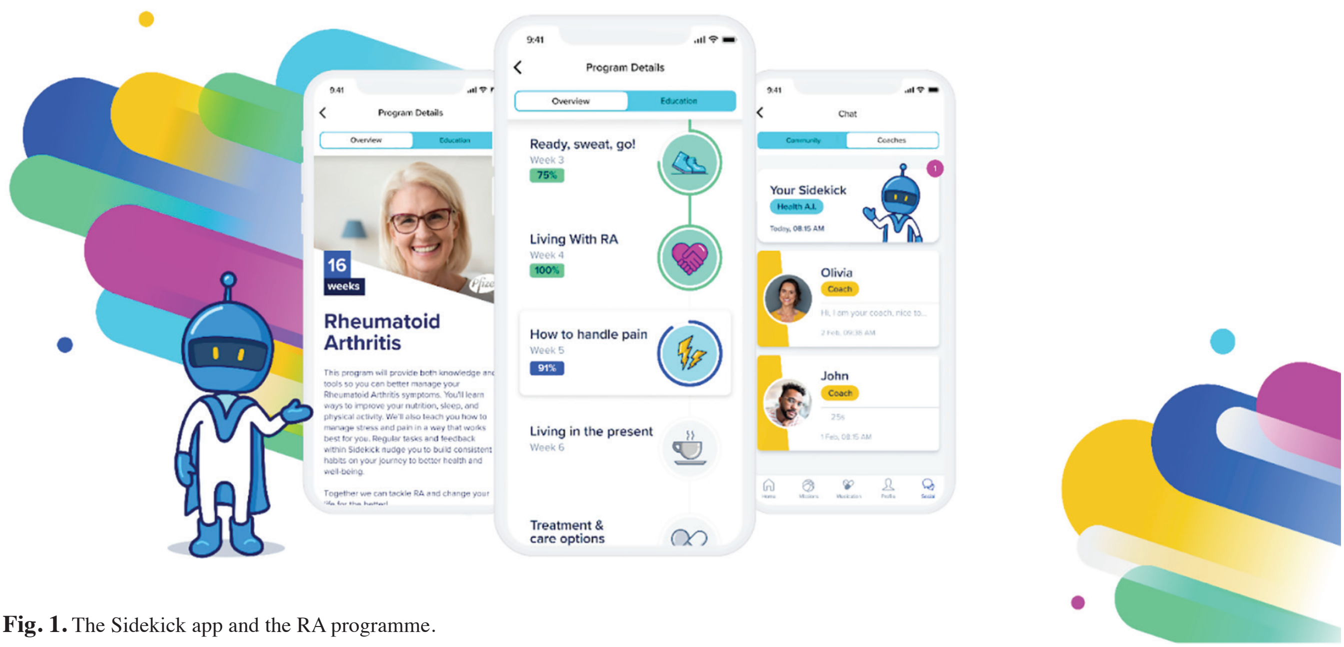


**Fig. 1.** The Sidekick app and the RA programme.

**Table I.** User demographics by engagement group.

| Variable | Highly engaged, n=158[1] | Less engaged, n=477[1] | *p*-value[2] |
|---|---|---|---|
| Age, years | 54 (44-61) | 54 (43-64) | 0.739 |
| (Missing, n) | 33 | 139 | |
| Weight, kg | 78 (68-93) | 77 (67-91) | 0.393 |
| (Missing, n) | 1 | 22 | |
| Height, cm | 166 (162-170) | 166 (161-170) | 0.741 |
| (Missing, n) | 6 | 20 | |
| Gender | | | 0.881 |
| Female | 120 (95.2) | 320 (96.1) | |
| Male | 6 (4.8) | 13 (3.9) | |
| (Missing, n) | 32 | 144 | |

[1] median (IQR); n (%) for gender.
[2] Wilcoxon rank sum test; Pearson's Chi-squared test.

**Table II.** Characteristics of use and engagement with the 16-week Sidekick Health digital RA programme.

| Variable, median (IQR) | Highly engaged, n=158 | Less engaged, n=477 |
|---|---|---|
| Total activities | 560 (160-1258) | 52 (16-271) |
| Active days | 51 (18-104) | 8 (3-50) |
| Active weeks | 12 (4-16) | 4 (2-15) |
| Average weekly activities | 52 (37-81) | 15 (6-29) |
| Move missions | 76 (29-186) | 9 (2-57) |
| Mind missions | 114 (37-207) | 12 (3-70) |
| Food missions | 160 (48-456) | 15 (3-92) |
| Education missions | 56 (17-133) | 8 (2-36) |

to address the needs of individuals with RA and reduce the burden on healthcare providers. The European League Against Rheumatism (EULAR) guidelines also recommend digital healthcare for self-management (10).

Digital support programmes generate real-world data (RWD), which can be utilised to validate the EULAR recommendation. RWD is routinely-collected individual-level longitudinal data, which can be used to analyse the effects of healthcare interventions (12). Different from traditional randomised-controlled trials, RWD can capture broader populations' day-to-day experiences, unconstrained by a clinical trial setting.

In 2021 Sidekick Health, a digital therapeutics company, launched a 16-week digital support programme for people with RA. Observations from the first eight weeks of the programme were previously presented (13). The present analysis reports the real-world evidence (RWE) generated from data collected over two subsequent years. The objective was to understand whether QoL improved for users engaged with the programme in a real-world setting.

## Methods

### *Users*

Data from users of the 16-week RA programme between January 12, 2021 and March 24, 2023 were retrospectively analysed. The Finnish Rheumatism Association helped to distribute the free programme to RA patients in Finland. Users downloaded the app to their smartphones, consented digitally to research and optionally entered baseline characteristics. Eligible users were ≥18 years. Data were anonymised before extraction. This analysis included 635 activated users who continued to engage with the programme after the first week, out of 1541 enrolled. Although the clinical characteristics of patients were not collected, it was assumed that only RA patients would be motivated to participate after week one, due to the clinically relevant content. "Tourists" without an RA diagnosis would not be motivated. Therefore, the analysis set

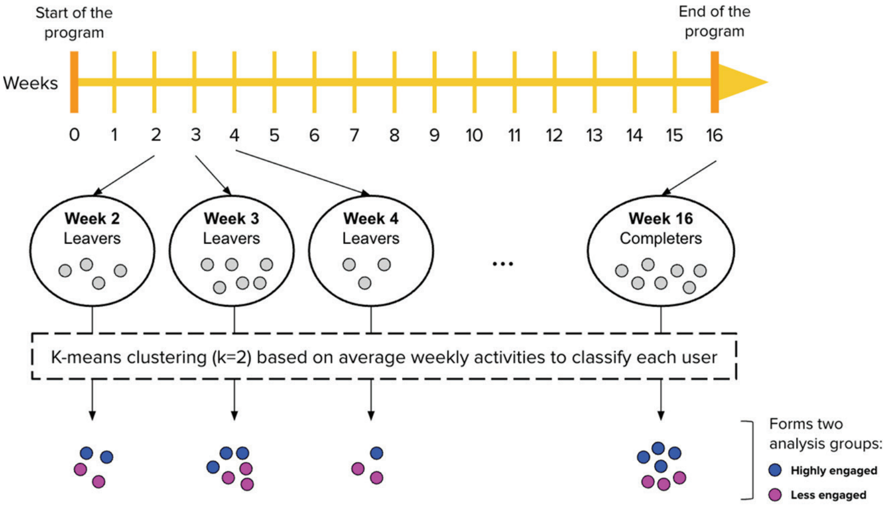


**Fig. 2.** Iterative weekly clustering based on average weekly activities ensured more robust user grouping than clustering at the end of the programme only. Preserving a similar number of clustered users in both groups each week may counter potential survival bias caused by non-completion impact.

excluded users who were only active in week 1.

*Programme*
Users completed daily missions towards healthy lifestyle habits target specifically to rheumatoid arthritis: 'food' (promoting a healthy diet), 'move' (engaging in physical activity), 'mind' (practices for positive emotions and self-care), 'sleep' (techniques to improve sleep) and rheumatoid arthritis-specific education, such as pain management and tools to enhance treatment and care. The programme included weekly feedback messages from a coach on logged missions. The general programme is also described in our previous publications, *e.g.* (14).

*Assessments*
Measures of QoL (stress, energy, sleep quality) were self-reported on an in-app Likert scale (0–10) up to four times per week; scores were aggregated by week. Engagement was measured by number of in-app activities completed, number of active days and weeks (engagement with the app at least once per day or week, respectively), and number of completed missions.

*Statistical analysis*
*- Survival bias*
Survival bias would be present if QoL scores were lower among non-completers than those who remained in the programme. To evaluate potential bias, a pre-post paired t-test was conducted to confirm improvements in both the complete case cohort (users who completed the programme) and the full analysis cohort (all users, with last observations carried forward).

*- Clustering*
Users were divided into highly-engaged and less-engaged groups each week based on the average number of weekly activities using iterative *K*-means clustering (*k*=2) (15) (Fig. 2).

*- Mixed models for repeated measures*
Mixed models for repeated measures (MMRM) were used to estimate changes in energy, stress, and sleep quality for highly- *versus* less-engaged groups. The MMRM uses all available data to provide unbiased estimates based on the maximum likelihood under the missing at random assumption (MAR). Assessed models included fixed variables (age, time (continuous, logarithmic, or quadratic), group, and time-group interaction) and user-specific random intercepts. Optimal models were determined by likelihood ratio tests. Interactions between groups and factors of interest were considered significant below an alpha-level of 0.10 (two-sided). All other tests were two-tailed and considered significant below an alpha-level of 0.05.

## Results

*Demographics*
Groups did not differ significantly across demographic variables (n=158 highly-engaged; n=477 less-engaged) (Table I).

*Use and engagement*
Highly-engaged users completed a median (IQR) of 560 activities (160-1258) throughout the programme and were active for 51 days (18–104). Less-engaged users completed 52 activities (16-271) and were active for 8 days (3–50) (Table II).

*Survival bias*
The full analysis set (n=635) had significant pre-post differences (mean; 95% CI; paired t-test) in self-reported energy levels (0.46; 0.33–0.60; $p<0.001$), stress (0.40; 0.23–0.57; $p<0.001$), and quality of sleep (0.21; 0.06–0.36; $p=0.006$). Comparably, in the complete case set (n=164), significant differences were found for energy (0.61; 0.37–0.85; $p<0.001$) and stress levels (0.56; 0.27–0.85; $p<0.001$), but not for sleep (0.16; -0.10–0.43; $p=0.200$).

*Quality of life*
Highly-engaged users achieved better scores in energy, stress, and sleep than less-engaged users (MMRM results; Fig. 3), indicated by significant group coefficients (Supplementary Table S1) and estimated between-group mean differences for all QoL outcomes with the largest absolute value of effect size in energy levels ($d_{abs}$=0.68) and the lowest for stress ($d_{abs}$=0.35) (Table III). Both groups experienced significant improvements in all QoL outcomes over time, indicated by the significant quadratic time terms and positive linear time terms for energy and sleep, and negative for stress, after centering (Suppl. Table S1). The significant time-group interaction was found only for sleep levels.

*Energy*
Analysis of energy levels revealed significant main effects of age ($F(1,375)=4.31$, $p=0.039$), quadratic time ($F(2,2632)=53.06$, $p<0.001$), and group ($F(1,368)=14.92$, $p<0.001$). The time-group interaction was not sig-

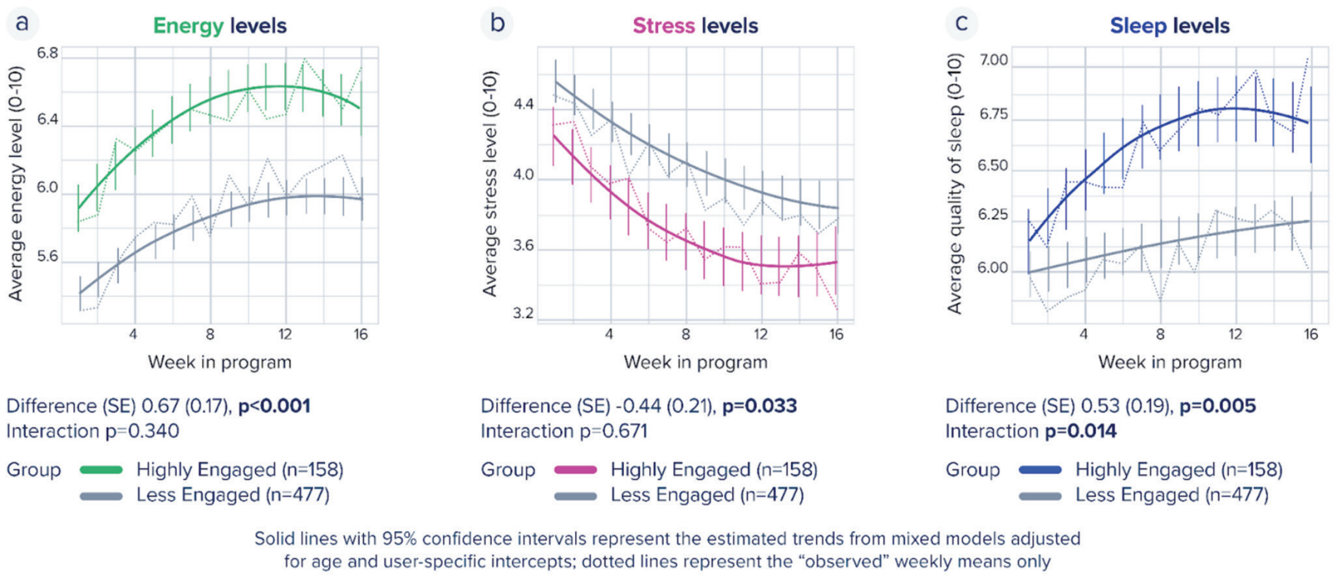


**Fig. 3.** Quality of life over time by engagement group (a=Energy; b=Stress; c=Sleep). Solid lines with standard error bars represent the estimated trends from mixed models adjusted for age with user-specific intercepts. The dotted lines represent the observed weekly means. Estimates show that highly-engaged users achieved better scores across the programme in energy, stress, and sleep than less-engaged users.

**Table III.** Within-group and between-group estimates of QoL outcomes over time from MMRM.

| | Estimated within-group mean (SE), across programme | | Estimated between-group mean difference (SE), across programme | | | Time-group interaction effect | |
|---|---|---|---|---|---|---|---|
| | Highly engaged (n=158) | Less engaged (n=477) | Highly *vs.* less engaged | *p*-value | Cohen's d (95% CI) | F | *p*-value |
| Energy | 6.500 (0.135) | 5.827 (0.100) | 0.673 (0.168) | **<0.001** | 0.68 (0.35–1.02) | 1.079 | 0.340 |
| Stress | 3.706 (0.164) | 4.144 (0.123) | -0.438 (0.205) | **0.033** | -0.35 (-0.68–(-0.03)) | 0.399 | 0.671 |
| Quality of sleep | 6.658 (0.152) | 6.125 (0.113) | 0.533 (0.190) | **0.005** | 0.45 (0.14–0.77) | 4.288 | **0.014** |

SE: standard error; CI: confidence intervals; F: F-statistic from ANOVA summary of MMRM; significant *p*-values are in bold.

nificant ($F(2,2632)=1.08$, $p=0.340$), which indicates that the groups differed in their average energy levels, but the magnitude of the change over time was similar between the groups. The main effects of age, time, and group remained significant after removing interaction from the model.

*Stress*

Analysis of stress levels revealed significant main effects of age ($F(1,365)=7.26$, $p=0.007$), quadratic time ($F(2,2628)=42.69$, $p<0.001$), and group ($F(1,355)=4.06$, $p=0.045$) without significant interaction ($F(2,2629)=0.40$, $p=0.671$). The main effects of age and time remained significant after removing interaction from the model.

*Sleep*

For sleep levels, we found significant main effects of age ($F(1,374)=4.15$, $p=0.042$), quadratic time ($F(2,2665)=16.81$, $p<0.001$), and group ($F(1,364)=6.91$, $p=0.045$) with significant interaction ($F(2,2665)=4.29$, $p=0.014$), which indicates that the effect of engagement on sleep differed between groups over time: highly-engaged users not only had better sleep scores, but they also experienced larger improvements over time than less-engaged users.

## Discussion

In this RWD analysis, we found that users of Sidekick Health's 16-week RA programme experienced significant improvements in energy, stress and sleep quality. This builds on prior results from the eight week timepoint (13). Users who actively engaged with the programme consistently achieved higher QoL scores compared with less-engaged users. For sleep quality, highly-engaged users had larger and faster improvements than less-engaged, while for energy and stress, level of engagement did not affect the magnitude of changes. This is the first RWE publication from a digital support programme for RA; results demonstrate that the programme is not only feasible, but successful in improving QoL for people with RA in the real world. This supports 2021 EULAR recommendations (10) to incorporate digital support into the care of people with inflammatory arthritis.

To improve the validity of evidence generated by RWD, we applied methods to identify and address potential survival bias. Pre-post tests of completers and non-completers suggested comparable QoL, and iterative weekly clustering lessened the impact of non-completion.

This analysis had several limitations. The programme was distributed through clinical channels, but the RA status of users was not confirmed; no disease-specific clinical data were recorded, which, given the heterogeneity of RA (2), may mean we studied only a subset of people with RA. We did however confirm that the age of our cohort was representative of Finnish RA patients (16) as well as excluding users who would likely be tourists. In addition, the QoL Likert scale was not a validated questionnaire; future analyses will compare this scale with common validated tools. Further, our cohort was ~95% female and based only in Finland which limits generalisability. Another limitation of our study is the presence of missing data, a common challenge in real-world research (17). However, measures (MMRM, iterative weekly clustering) were implemented to mitigate potential bias due to missingness.

## Conclusion

These findings highlight the potential of digital support programmes to address the complex needs of people living with RA. Significant improvements in energy, stress and sleep quality were observed among users, with methods to account for potential survival bias. Continued investment into digital support programmes may further improve patient self-management and encourage a more holistic, patient-centered approach to care, in a modern treatment environment where patient empowerment is increasingly relevant.

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