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Abstract

Background: Traditional in-clinic methods of collecting self-reported information are costly, time-consuming, subjective, and often limited in the quality and quantity of observation. However, smartphone-based Ecological Momentary Assessments (EMA) provide complementary information to in-clinic visits by collecting real-time, frequent, and longitudinal data that are ecologically valid. While these methods are promising, they are often prone to various technical obstacles. Yet the availability and interoperability with different operating systems (OSs) need to be fully resolved in existing solutions. This shortness increases the selection bias, development and maintenance costs, and time. It also limits the configurability and adoption of existing solutions to new problems.

Objective: The primary aim of this research was to develop a cross-platform EMA application that ensures a uniform user experience and core features across various OSs. Emphasis was placed on minimizing the resources and expenses associated with the development and maintenance and maximizing the integration and adaptability in various clinical trials, all while maintaining strict adherence to security and privacy protocols. JTrack EMA+ was designed and implemented in accordance with the FAIR principles (findable, accessible, interpretable, and reusable) in both its architecture and data management layers, thereby reducing the burden of integration for clinicians and researchers.

Methods: "JTrack-EMA+" is built using the Flutter framework, enabling it to run seamlessly across different platforms. This platform comprises two main components. JDash is an online management tool created using Python with the Django framework. This online dashboard offers comprehensive study management tools, including assessment design, user administration, data quality control, and a reminder casting center. And JTrack-EMA+ application supports a wide range of question types, allowing flexibility in assessment design. It also has configurable assessment logic and the ability to include supplementary materials for a richer user experience. It strongly commits to security and privacy and complies with the General Data Protection Regulations (GDPR) to safeguard user data and ensure confidentiality.

Results: We investigated our platform in a pilot study with 480 days of follow-up to assess participants' compliance. The six-month average compliance was 49.34%, significantly declining ($P<0.05$) from 66.75% in the first month to 42.0% in the sixth month. These results show the potential of using our newly introduced platform in remote and at-home-based EMA assessments.

Conclusions: : JTrack EMA+ platform is a pioneer in prioritizing platform-independent architecture that provides an easy entry point for clinical researchers to deploy EMA in their respective clinical studies. Remote and home-based assessments of EMA using this platform can provide valuable insights into patients' daily lives, particularly in a population with limited mobility or inconsistent access to healthcare services.

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Keywords: digital biomarkers; mobile health; remote monitoring; smartphone.

Introduction

Self-reported information in psychiatric disorders plays a crucial role in clinical decision-making. They are often gathered through traditional questionnaires or verbal conversations during clinic visits (1). These visits are infrequent, costly, and inaccessible to everyone (2). The self-reports from in-clinic visits may also be subject to higher recall bias, notably when asked to recall past memories and events (3).

The need to reduce reliance on traditional in-clinic visits and the widespread adoption of smart devices (such as smartphones and smartwatches) have increased their potential for use in clinical settings. Health-related data collected from these devices are often referred to as Digital Biomarkers (DBs) (4–6). DBs include a wide range of measurements, with Ecological Momentary Assessments (EMA) being one of the most widely accepted and utilized (7). EMA involves using experience sampling methods (ESM), which are brief assessments administered in real-time in naturalistic settings to study the moment-to-moment fluctuations of states and behaviors (8). EMA offers several advantages over traditional in-clinic visits, including a larger sampling frequency, the ability to collect longitudinal data, enhanced engagement, lower costs, and increased ecological validity (1,9). Smartphone-embedded sensors (e.g., location, pedometer, proximity, and luminance sensors) can also be used to trigger surveys in response to particular physical activities, changes in environmental factors, or behaviors, known as "event-based EMA " (10).

Assessment questions, supporting material (e.g., images, videos, and explanatory text), managing assessment logic (i.e., scheduling, inclusion/exclusion criteria, validating input answers, recording timestamps, storing and transferring assessments), and providing assessment completion reminders (11) are among the main features typically integrated into EMA applications. These advanced capabilities offer an excellent opportunity for collecting DBs in remote assessments. However, their implementation comes with several technical challenges and obstacles. These challenges include but are not limited to privacy and security, memory and battery usage, patient acceptance, scalability, and interoperability with different devices and operating systems (OSs). Although there are various applications intended to meet many of the above-mentioned criteria (12–16), interoperability with different OSs, adaptability, and configurability are still lacking. Several OSs are available for mobile (Android, iOS) and desktop (Windows, macOS) devices. Each of these has its own paradigms and programming languages. Therefore, separate developers and experts are required for each, significantly increasing the cost and development time. Also, restricting the applications to a specific OS may lead to a selection bias. A platform-independent architecture addresses these limitations. This motivated us to introduce JTrack-EMA+ as a cross-platform, configurable application that also complies with GDPR. It consists of an EMA application and an online management tool facilitating assessment management and data quality control. It is integrated into our previously introduced sensor-based DBs ecosystem, "JTrack" (17). In this paper, we also evaluated a pilot study using JTrack-EMA+ in a population of parents with a newborn to investigate participants' compliance with the assessment protocols.

[Figure 1]
[Figure 2]

[Figure 3]
[Figure 4]

Methods

Here, we describe the primary component of the JTrack platform for EMA (Figure 1), which includes a smartphone-based application (Figure 2) and an online management application, JDash (Figure 3,4). JTrack-EMA+ was developed based on platform-independent architecture using the Flutter framework (18). It reduces development and maintenance time, provides a consistent performance and user experience, and enables instant delivery of new feature updates and enhancements across multiple platforms.

Adaptability, and configurability

The behavior and performance of software are significantly impacted by rapidly evolving OSs. Being able to adapt to these changes in agile is a crucial trait that the platform-independent architecture of JTrack-EMA+ provides. Besides architectural benefits, JTrack-EMA+ constructs evaluation materials and logic using a JSON file to facilitate reusability and configurability. After users register with the provided QR codes, the assessment is generated based on a study-specific JSON file received from the server. Additionally, assessments can be updated remotely using this file without updating the application. The browser-based study management dashboard JDash has a built-in EMA creator to generate these JSON files making the design and configuration of an EMA study quite simple and versatile (Figure 4).
JTrack-EMA+ supports a wide range of assessment formats, such as binary, multiple-choice, text, or numeric user input, date and time, and sliding questions (Figure 2). It also maintains a configurable assessment logic (employing conditional questions, categorization, and customizable question frequency). This feature determines whether questions should be asked or ignored based on defined criteria (i.e., the time since the assessment began, the time of day, and the value or date of the response). It also supports on-demand questions.
JTrack-EMA+ supports two distinct paging styles: page-view and list-view. With page-view, participants will see a single question at a time, whereas list-view shows all questions as a list, allowing participants to expand (choose) a question to answer. While page-view ensures the visibility of each question, list-view is especially helpful in situations where many questions are shown or only specific questions are relevant.

Data quality, privacy, and security

Quality, security, and privacy of the collected data are important considerations when designing a novel EMA application. To address the data quality, syntactic input validation is deployed to ensure that only properly formed data is entered. Also, to prevent possible data loss, we adopted the "local-first" data storage method, where data is stored locally on the device and only synced to the server when connected to the internet. In addition, to mitigate the impact of potential interruptions (e.g., by other programs, battery drain, or phone restart) on saving data, we implemented an auto-saving mechanism.
To ensure data privacy and security and to comply with the EU General Data Protection Regulation (GDPR), JTrack-EMA+ deployment does not require any identifiers or personal data. All data is assigned to a JDash-generated user ID allowing for fully anonymized and pseudonymized data collection. Secure channels are utilized for communication between servers and devices, and data integrity is protected against unintended corruption and potential interruptions using MD5 algorithms. Moreover, the distribution of the application through official channels (i.e., Google Play Store and Apple App Store) provides convenience to the participants and creates a sense of security and confidentiality.

QR code-based registration, embedding control, and authentication methods streamline the registration process (these codes are generated when a study is created in JDash). In addition, we have provided a "leave study" option in the application, which enables all participants to withdraw from the study at any time.

Study management

JDash is an online study management application designed to assist JTrack study owners in creating new studies and managing ongoing ones (Figure 3). It allows study owners to create and modify all study aspects, such as the duration, add assessment materials (e.g., images), data quality checks, remove participants from a study, end a study, and manage the study owner's access level. Python (Django and WSGI) was chosen as the implementation technology (19). JDash consists of a user interface and a backend. While the backend API serves as an endpoint for receiving, saving, and authentication requests arriving from the application, the frontend interface can also be used to create and design an assessment (Figure 1).

The JDash is created with a primary goal of making it easy to use and deploy. It is developed using flawless design principles, which provide a range of features for clinicians to establish their assessments intuitively. These principles hide unnecessary steps to make the usage even more efficient. In addition to an open-source software license, JDash uses an automated deployment model that is efficient, consistent, and error-prone. (For instruction on deployment, readers may refer to the documentation on our GitHub page, the link is provided in the data availability statement section) In addition, JDash has a comprehensive notification system to ensure periodic reminders based on a predetermined schedule, avoiding unwanted (e.g., overnight) alerts. This notification is designed to operate locally (offline) and as a push notification (online) that can be sent to participants' devices from the dashboard. This module is integrated into JDash to deliver reminders to participants' devices, either individually or based on their status (i.e., no data sent in a few days). This regular reminder has the potential to minimize the high dropout rate of EMA-based assessments (9).

Finally, most research programs aim to share data with colleagues or along with research results to promote transparency, encourage collaboration, and accelerate research. To facilitate this goal, we have used DataLad (20) as a data management infrastructure on our servers to manage data according to FAIR (findable, accessible, interpretable, and reusable) principles (21). Datalad offers essential features such as data versioning, metadata handling, structured formatting, and change tracking under an open-source license which contributes to enhanced security and privacy of collected data. This integration in the data management layer also accelerates reproducible science, a key element of scientific methods.

Pilot study

We deployed the JTrack EMA+ application in a pilot study involving 170 parents with newborns followed up for 480 days. The pilot study includes weekly assessments of children’s physical and mental development. To illustrate the development questions, a picture was shown for each question. The pictures were designed by Martin Pawlusiak. We've been conducting the pilot study since November 2021, and it's set to run until November 2023. As of now, we've released the preliminary compliance data that we've gathered over the first 14 months of the study. We calculated the compliance rate as a percentage of completed surveys compared to what was expected. In total, 65 participants completed assessments for at least six months and were included in the compliance analysis. Monthly compliance was computed as the number of received data points divided by the number of expected data points. Monthly average compliance was compared using the Friedman test, followed by pairwise comparisons using the Wilcoxon rank sum test.

[Figure 5]

Results

Figure 5 displays the fluctuation of average compliance rates across the six months of the pilot study. The overall average compliance rate across this period was 49.43%. The between-group comparisons of the average compliance rate show a significant decrease from 66.75% in the first month to 46.92% (*P*=0.011), 42.61% (*P*<0.01), 42.61% (*P*<0.01), 42.92% (*P*<0.01), and 42.0% (*P*<0.01) in the third, fourth, fifth, and sixth months, respectively.

Discussion

Here, we introduced JTrack-EMA+, a smartphone-based, real-time EMA application. This platform-independent architecture of the application reduces the disparity in user experiences and functionality across different OSs. It complies with the General Data Protection Regulations (GDPR) and official application distribution channels while providing all features required for designing and deploying EMA-based evaluations.

The online dashboard serves as a central study management interface. It visualizes and summarizes the study information (i.e., duration, the number of subjects, and supplementary information). This information is used for data streaming and quality checks and to interact with participants in case of missing or invalid data via push notifications. Researchers can control the access to the specific information of the study to their research partners through the user access level control provided by the dashboard. The open-source solution DataLad (20) is used for data management in JDash, and above mentioned functionalities reduce reliance on third-party applications and services such as Amazon Web Services (AWS).

The traditional development architecture used by existing platforms is limited by its shortcomings (12–16). A lack of support and disparities in user experience and application functionality across platforms are among the most significant contributors. Therefore, most EMA platforms are either available for a single OS (i.e., ULTEMAT is only available for Android (15), and iHabit is only available for iOS (16)) or have different features depending on the OS (i.e., AWARE, Radar-Based and SEMA3 have two distinct applications for each platform (12,14,22)). To the best of our knowledge, the JTrack-EMA+ stands out as a pioneer in prioritizing platform-independent architecture. This platform offers extensive configurability, which sets it apart from the existing platform. It also provides a flexible and dynamic environment instead of being limited to a single problem-oriented solution.

The effectiveness of EMA depends on the participants' motivation and adherence to assessment protocols (11,23). Poor compliance and missing data can adversely impact the quality of the collected data and introduce bias in the sample, thereby hindering the success of clinical applications. Our results revealed an overall average of 49.34% with a significant decrease in compliance rate after two months. Although there is a large degree of heterogeneity in compliance rates reported in various studies (24)), considering our inclusion time constraint (six months) and the target demographic (parents with busier routines who dedicate more time to their newborn), this compliance rate can be considered an acceptable rate. Overall, our results demonstrate the potential to use our platform compared to the paper-and-pencil EMA assessment (which was shown to have a significantly lower compliance rate), particularly in participants with limited mobility or restricted access to healthcare services (24).

A limitation of our platform is its ability to detect and respond to various events and contexts, such as environmental and physical activities. Although we consider this a limitation here, it is done on purpose to simplify the ethics and data privacy required by sensory and contextual assessment, required in addition to EMA. Also despite the attempts to keep performance and user experience consistent across all OSs, background work constraints in iOS may influence the app’s internal reminders on these devices, so automated push notifications implemented by JDash can be a better choice for such devices.

Finally, JTrack-EMA+ is an active project regularly updated to add new features and improve the platform's functionality. The features described here are part of the version 1 release. Therefore, later versions may have additional functions which will be documented with the respective releases. The most updated JTrack-EMA+ versions are released via the official distribution channels (i.e., Google's Play Store and Apple's App Store). All study management functionalities to deploy JTrack-EMA+ are implemented as an open source and can be accessed from our GitHub repository under an open-source license.

Conclusions

In this paper, we covered the key concepts associated with EMA applications and the technical constraints of existing platforms. Then we launched a platform-independent JTrack-EMA+ application to reduce the gap in user experience and application functionality across different OSs while adhering to security, privacy, and GDPR requirements.
In a pilot study, we also demonstrated participants' compliance rate with assessment protocols and how it fluctuated over a six-month course of study. We conclude that remote and at-home assessment utilizing this platform results in an acceptable rate of compliance that may not be possible using the conventional in-clinic visit method, particularly in a population with limited mobility or a busy schedule- as were the participants in our pilot study. Finally, we concluded that platform-independent architectures provide comparable functionality and user experience and save development and maintenance costs over time. These principles are critical to EMA-based assessments' effectiveness and applicability in clinical trials.

Ethics Statement

The studies involving human participants were reviewed and approved by the Ethics committee at the medical faculty, Heinrich-Heine-Universität Düsseldorf, Germany. The patients/participants provided their written informed consent to participate in this study.

Data Availability Statement

For the most updated and previous versions as well as technical documents, please visit the public repository accessible at https://github.com/Biomarker-Development-at-INM7.
Under iOS this application is published as JTrack-EMA.

Authors' Contribution

MSF developed the JTrack EMA+ application and performed all analyses. MSF wrote the manuscript with the support of JD. JMF and MN developed the online dashboard application. JD designed the overall study. SBE and TM contributed to the overall design of the study. DS contributed to the development of questions for the pilot study. RR and SS recruited probands and the clinic. All authors contributed to the article and approved the submitted version.

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Conflict of Interest

All the authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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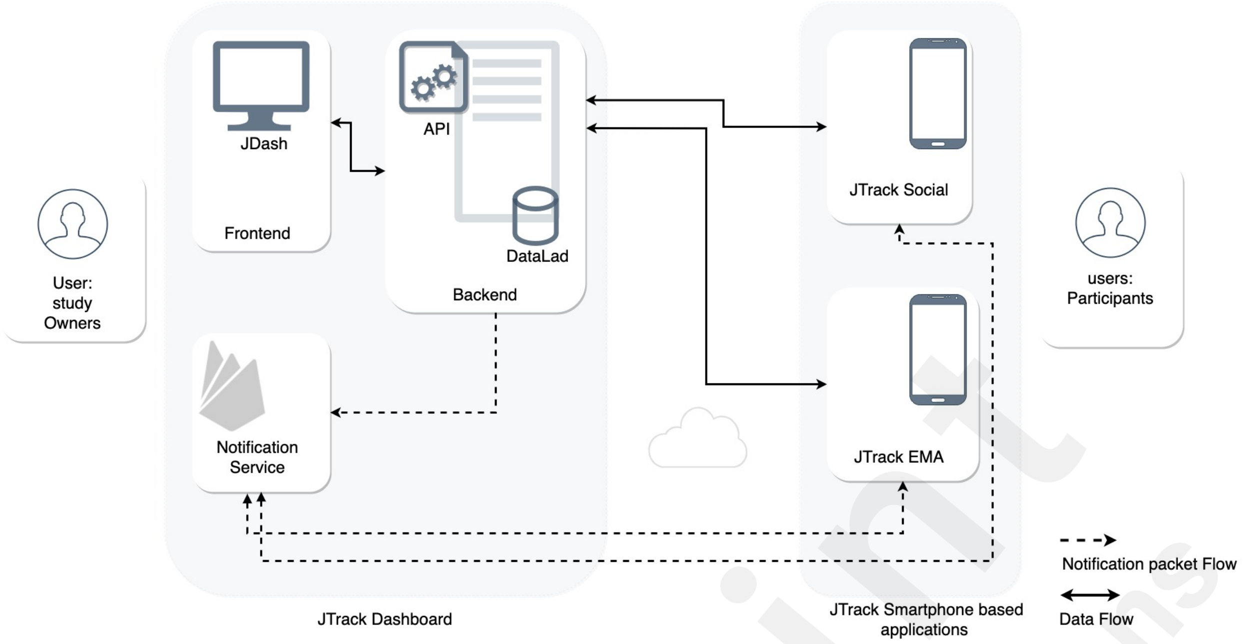
Abbreviations

OS: Operation System
DB: Digital Biomarker
GDPR: General Data Protection Regulation
EMA: Ecological Momentary Assessment
APP: Application
ESM: Experience Sampling Method
AWS: Amazon Web Services
MD5: Message Digest algorithm



JDash
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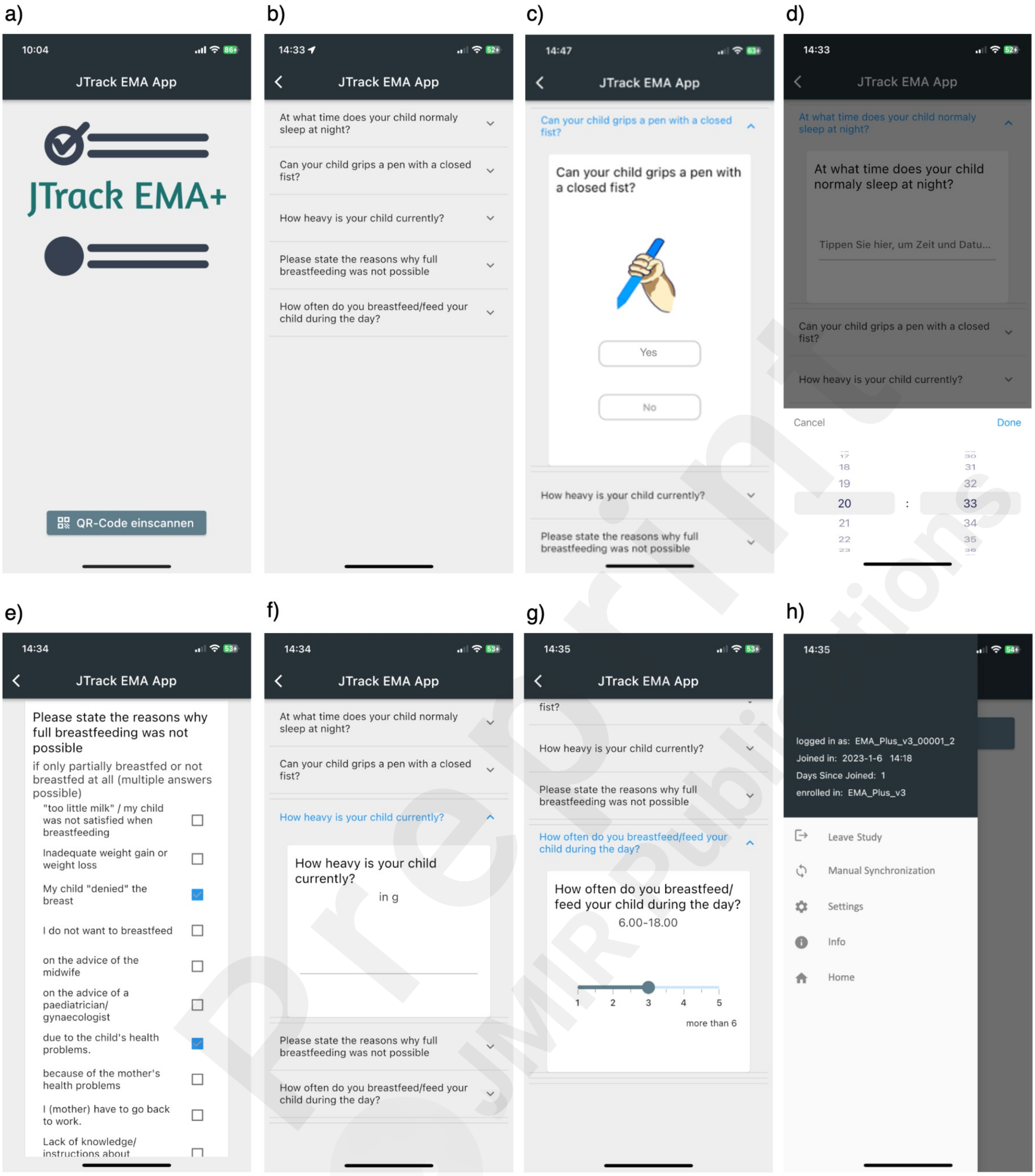
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JTrack EMA App
At what time does your child normaly sleep at night?
Can your child grips a pen with a closed fist?
How heavy is your child currently?
Please state the reasons why full breastfeeding was not possible
How often do you breastfeed/feed your child during the day?
c)
14:47
JTrack EMA App
Can your child grips a pen with a closed fist?
Can your child grips a pen with a closed fist?
Yes
No
How heavy is your child currently?
Please state the reasons why full breastfeeding was not possible
d)
14:33
JTrack EMA App
At what time does your child normaly sleep at night?
At what time does your child normaly sleep at night?
Tippen Sie hier, um Zeit und Datu...
Can your child grips a pen with a closed fist?
How heavy is your child currently?
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JTrack EMA App
Please state the reasons why full breastfeeding was not possible
if only partially breastfed or not breastfed at all (multiple answers possible)
"too little milk" / my child was not satisfied when breastfeeding
Inadequate weight gain or weight loss
My child "denied" the breast
I do not want to breastfeed
on the advice of the midwife
on the advice of a paediatrician/ gynaecologist
due to the child's health problems.
because of the mother's health problems
I (mother) have to go back to work.
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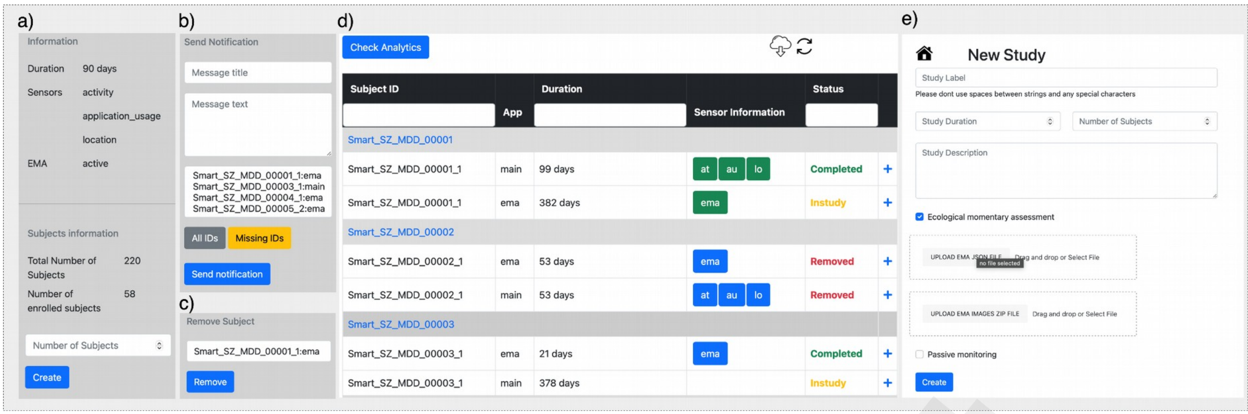
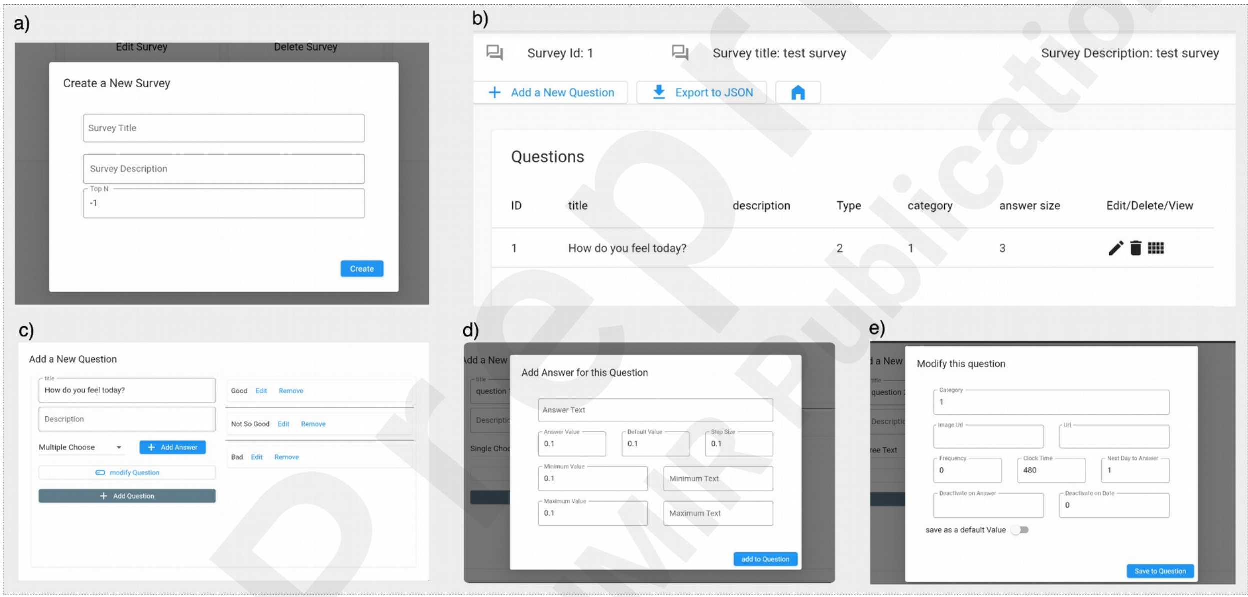
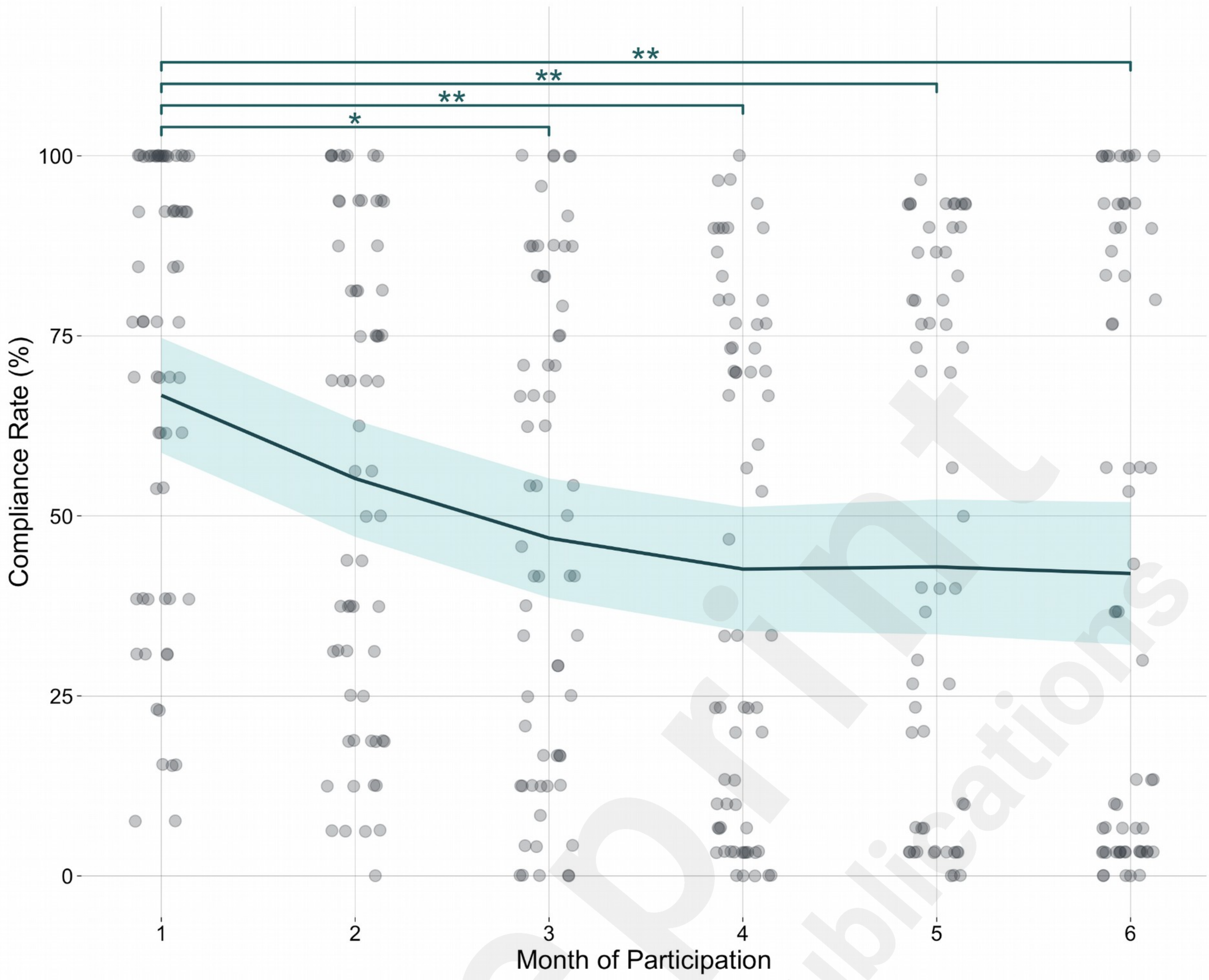
Info
Home


a)
Information
Duration 90 days
Sensors activity
application_usage
location
EMA active
Subjects information
Total Number of Subjects 220
Number of enrolled subjects 58
Number of Subjects
Create
b)
Send Notification
Message title
Message text
Smart_SZ_MDD_00001_1:ema
Smart_SZ_MDD_00003_1:main
Smart_SZ_MDD_00004_1:ema
Smart_SZ_MDD_00005_2:ema
All IDs
Missing IDs
Send notification
c)
Remove Subject
Smart_SZ_MDD_00001_1:ema
Remove
d)
Check Analytics
Subject ID
App
Duration
Sensor Information
Status
Smart_SZ_MDD_00001
Smart_SZ_MDD_00001_1 main 99 days at au lo Completed
Smart_SZ_MDD_00001_1 ema 382 days ema Instudy
Smart_SZ_MDD_00002
Smart_SZ_MDD_00002_1 ema 53 days ema Removed
Smart_SZ_MDD_00002_1 main 53 days at au lo Removed
Smart_SZ_MDD_00003
Smart_SZ_MDD_00003_1 ema 21 days ema Completed
Smart_SZ_MDD_00003_1 main 378 days Instudy
e)
New Study
Study Label
Please dont use spaces between strings and any special characters
Study Duration
Number of Subjects
Study Description
Ecological momentary assessment
UPLOAD EMA JSON FILE
Drag and drop or Select File
UPLOAD EMA IMAGES ZIP FILE
Drag and drop or Select File
Passive monitoring
Create


a)
Edit Survey
Delete Survey
Create a New Survey
Survey Title
Survey Description
Top N
-1
Create
b)
Survey Id: 1
Survey title: test survey
Survey Description: test survey
Add a New Question
Export to JSON
Questions
ID
title
description
Type
category
answer size
Edit/Delete/View
1
How do you feel today?
2
1
3
c)
Add a New Question
How do you feel today?
Description
Multiple Choose
Add Answer
modify Question
Add Question
Good Edit Remove
Not So Good Edit Remove
Bad Edit Remove
d)
Add Answer for this Question
Answer Text
Answer Value
Default Value
Step Size
0.1
Minimum Value
Minimum Text
Maximum Value
Maximum Text
add to Question
e)
Modify this question
Category
1
Image Url
Url
Frequency
0
Clock Time
480
Next Day to Answer
1
Deactivate on Answer
Deactivate on Date
0
save as a default Value
Save to Question


**
**
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*
100
75
50
25
0
Compliance Rate (%)
1
2
3
4
5
6
Month of Participation