
Patrick-Pascal Strunz
Strunz_P@ruw.de

University Hospital Würzburg, Department of Internal Medicine 2, Rheumatology/Clinical Immunology, Oberdürrbacher Straße 6, 97080 Würzburg, Germany

Maxime Le Maire
University of Würzburg, Medical Faculty, Josef-Schneider-Straße 2, 97080 Würzburg, Germany

Tobias Heusinger
University of Würzburg, Medical Faculty, Josef-Schneider-Straße 2, 97080 Würzburg, Germany

Juliana Klein
University of Würzburg, Medical Faculty, Josef-Schneider-Straße 2, 97080 Würzburg, Germany

Hannah Labinsky
University Hospital Würzburg, Department of Internal Medicine 2, Rheumatology/Clinical Immunology, Oberdürrbacher Straße 6, 97080 Würzburg, Germany

Anna Fleischer
University Hospital Würzburg, Department of Internal Medicine 2, Psychosomatic Medicine, Oberdürrbacher Straße 6, 97080 Würzburg, Germany

Karsten Sebastian Luetkens
University Hospital Würzburg, Department of Diagnostic and Interventional Radiology, Oberdürrbacher Straße 6, 97080 Würzburg, Germany

Patricia Possler
University of Würzburg, Medical Faculty, Josef-Schneider-Straße 2, 97080 Würzburg, Germany

Michael Gemert
University Hospital Würzburg, Department of Internal Medicine 2, Rheumatology/Clinical Immunology, Oberdürrbacher Straße 6, 97080 Würzburg, Germany

Robert Leppich
Chair of Software Engineering (Informatik II), Department of Computer Science, University of Würzburg, Am Hubland, 97074 Würzburg, Germany

Astrid Schmieder
University Hospital Würzburg, Department of Dermatology, Venereology, and Allergology, Josef-Schneider-Straße 2, 97080 Würzburg, Germany

Ludwig Hammel
Deutsche Vereinigung Morbus Bechterew e. V., Metzgergasse 16, 97421 Schweinfurt, Germany.

Evelin Schulz
Deutsche Vereinigung Morbus Bechterew e. V., Metzgergasse 16, 97421 Schweinfurt, Germany.

Billy Sperlich
Integrative and Experimental Exercise Science and Training, Institute for Sports Science, University of Wuerzburg. Judenbühlweg 11, 97082 Würzburg, Germany

Matthias Froehlich
University Hospital Würzburg, Department of Internal Medicine 2, Rheumatology/Clinical Immunology, Oberdürrbacher Straße 6, 97080 Würzburg, Germany

Marc Schmalzing
University Hospital Würzburg, Department of Internal Medicine 2, Rheumatology/Clinical Immunology, Oberdürrbacher Straße 6, 97080 Würzburg, Germany

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Abstract

Background

Patients with axial spondyloarthritis (axSpA) benefit from regular home-based exercise (HbE). In spite of recommendations, a relevant proportion of German axSpA patients does not adhere to recommended HbE practices. To enhance HbE care, we developed the novel digital therapeutic (DTx) "Axia" compliant with the European medical device regulation (MDR). Axia offers a modern app-based HbE solution with patient educative content and further integrated features. A first patient survey involved axSpA patients who assessed Axia’s efficacy, attractiveness, and functionality through a questionnaire.

Methods

A mixed-method online questionnaire with 38 items was administered to 37 axSpA volunteers after using Axia. Numeric rating scales (NRS) and likelihood scales were primarily used.

Results

Axia received a median rating of 5 out of 5 stars. On NRS scales, Axia scored a median of 9 for intuitiveness and design, and a median of 8 for entertainment. HbE frequency significantly increased from a median of 1 day/week to 6 days/week (p<0.001). Existing HbE practitioners also increased their frequency (median of 4 days/week before, 6 days/week with Axia, p<0.05). 64.9% reported improved range of motion, 43.2% reported reduced pain, and 93.6% enhanced disease-specific knowledge. All users recommended Axia to other patients.

Conclusion

Axia represents a promising DTx for axSpA, warranting further investigation in large randomized controlled interventional trials to establish its efficacy conclusively.

Background

Smartphone accessibility has led to the widespread use of mobile exercise apps, with one-third of German adults and half of those under 30 utilizing them according to the WSB-market study by Fittkau and Maaß (1). In conjunction with this trend, app-based digital therapeutics (DTx) focusing on exercise-related therapy are becoming more integrated into healthcare, particularly for patients needing consistent physiotherapy and exercise routines.

Among rheumatic diseases, axial spondyloarthritis (axSpA), a chronic inflammatory disease of the axial skeleton, has the strongest recommendation for regular disease-specific exercise programs: Exercise therapy is mentioned as one of the two central therapeutic pillars besides pharmacotherapy in national and international guidelines (2). Besides training in physical therapy facilities and self-help groups, home-based disease-specific exercise programs have shown to improve disease activity (BASDAI) disease-specific functionality (BASFI), range of motion (BASMI) and quality of life (ASQoL, SF-36) (3) (4) (5) (6). Despite these recommendations, a recent survey found that nearly 30 percent of German axSpA-patients exercise too infrequently (7). This trend has been further exacerbated by the closure of physical therapy facilities, fitness centers, and self-help groups during the SARS-CoV-2 pandemic (7).

With all this in mind, it is apparent that a DTx for axSpA might have enormous potential to support patients in their individual (exercise) therapy by improving their care situation.

The prospect of bridging the existing healthcare gap with a suitable digital therapeutic (DTx) appears even more promising in light of a novel approach adopted in Germany about three years ago, which has since received increasing international attention: In the German healthcare system, innovative DTx that demonstrate a clinical benefit in patient care and pass a central approval process can be prescribed by physicians, similar to medication, and are eligible for reimbursement by all Statutory Health Insurances. DTx successfully passing this approval process are known as "Digital Health Applications" (DHA, or "Digitale Gesundheitsanwendungen" in German) and are included in an exclusive directory, the "German DIGA Verzeichnis," managed by the German authorities (DHA directory) (8). Being listed in this directory is a mandatory requirement for a DTx to be reimbursed by all health insurance companies.

With the aforementioned facts in mind, we decided to develop a DTx for people affected by axSpA. The primary goal was to focus on axSpA-specific exercise therapy as the core of the application. The potential of this approach is further evidenced by recent findings revealing that axSpA patients benefit from using general exercise DHAs designed for back pain (9). Initially, we surveyed 435 German patients with axSpA from the German patient self-help association "Deutsche Vereinigung Morbus Bechterew" (DVMB) to assess the need for an axSpA-specific DHA (7). In this survey, 84% of the participants expressed their wish for such an app and provided extensive feedback on the essential functionalities an axSpA-focused app should include.

Reviewing different DHA listed in the German DHA directory for other diseases than axSpA revealed that a specific DHA for axSpA might provide further benefits beyond direct therapeutic exercise interventions (8): Some DHA approved for different conditions have been proven to enhance patient care by providing disease-specific educational information as well as behavioral therapeutic approaches (8). We considered these factors especially helpful when addressing important comorbidities of axSpA like insomnia, fatigue, anxiety, or distress (2) (10) (11) (12). Furthermore, features like symptom tracking or medication-reminder functions can improve patients’ self-management (10) (11). Therefore, our approach was to develop a holistic app delivering disease-specific exercise programs while also incorporating elements of coaching, behavioral therapy, and self-management features to improve multiple aspects of quality of life for patients with axSpA. To involve the German axSpA patients into the development process, the app called "Axia" was developed in close cooperation between the manufacturer and the DVMB with additional scientific support by the University Hospital of Wuerzburg. Combining all the above features, Axia has already been labeled as a medical device in 2023. In this article, we want to present Axia and report the promising results of a first user survey.
Methods

Development process and Design of Axia

Axia is a class I medical device that was developed by Applimed (Aachen, Germany), a startup founded by medical students, in close cooperation with the University Hospital of Würzburg and the DVMB.

The app's design and content are based on a market analysis of other approved DHAs (8), the results of a survey among 435 axSpA patients (7), individual interviews with more than 50 patients, and recommendations from rheumatologists at the University Hospital of Würzburg. In addition, several physical therapists specialized in axSpA were closely involved in the development of all exercise programs. To make Axia available for both iOS and Android devices, the cross-platform framework Flutter was used. So far, Axia is only available in German language. Figure 1 gives an overview of the user interface.

Providing guideline-based exercise therapy

Axia does not only offer individually tailored exercise programs for axSpA-patients, but also encourages them to adopt short daily exercise habits, engage in sports, and achieve a daily step goal. This promotes a holistic approach to exercise therapy and an active and sporty lifestyle in line with the guidelines (2).

The core of the Axia app features a variety of exercise programs offering exercise suggestions tailored to the patient's flexibility, pain regions, age, and already existing movement restrictions. Axia includes a unique learning algorithm that continuously adapts the therapy to patient feedback by individually selecting optimal exercises from a comprehensive training catalog. For this purpose and under the guidance of specialized physical therapists, more than 250 exercise videos were professionally produced using multiple camera angles to present the correct way of exercise performance. In an initial instructional video, the patient is first given an explanation of each exercise. Afterward, the narrator guides the patient through the exercise while providing additional coaching to ensure correct execution. Figure 2 presents an example of a typical exercise video.

Besides individualized exercise programs designed to maintain flexibility, upright posture, and pain relief over the long term, Axia also offers tailored exercises for acute pain and morning stiffness based on the patient's current pain location and aggregated data, with the goal of providing quick relief to the patient in painful situations. In additional "intensive training" sessions, the user can further choose exercise programs with higher intensity for also addressing cardio-fitness.

To further promote physical activity in everyday life, Axia encourages patients to incorporate small exercise habits into their daily routine. Using a pedometer integrated into Axia, the patients can track a self-imposed step target using their smartphones or a wearable as a sensor. Finally, Axia offers a documentation function for sports activities and physiotherapy sessions.

Motivation and Gamification to achieve long-term adherence

Maintaining a high level of patient adherence is one of the most important and challenging factors for the success of DTx (13). For this reason, Axia not only focuses on proven methods of motivational psychology, such as the acquisition of long-lasting habits, but also on a gamification concept for the app with a rewarding and individualized points system for exercise therapy activities. In addition, an animated mascot named "Bechto" motivates the patients with humorous animations and encouraging messages. Patients are also motivated to achieve milestones and streaks, completing the gamification concept of the app. A notification system reminds patients of their exercise, especially when they are at risk of missing their exercise goals (The mascot as well as the "points tank" are presented in Fig. 1).

Information on the disease and axSpA management

In a knowledge library with 56 interactive learning articles, the patients receive information on important disease-related topics and how to optimize daily life with axSpA. The library is divided into courses, each containing between two and nine interactive learning units. Courses cover a broad range of topics, such as explanations of the clinical presentations and therapies, the importance of exercise for axSpA patients, improvement of sleep quality, management of disease flares, information on medication and nutrition, and other related topics. There is also a dedicated course that provides the most essential information for newly diagnosed patients.

Symptom tracking, progress dashboard and other features

Axia allows patients to make regular symptom queries including pain levels, patient global assessment (PGA), and stress levels. On a progress tracker dashboard, patients can see the development of their symptoms as well as their activity level in Axia for different time frames (last 7/30 days and last 3/6/12 months). Patients can also export a progress report as a PDF file. To assist patients in managing difficult situations and learning relaxation techniques, a variety of relaxation exercises are available, such as progressive muscle relaxation, autogenic training, and brief relaxation exercises. Patients can also monitor their medication using the medication function.

Study Design

After the above-mentioned development process, the CE marking of Axia as a medical device was achieved in June 2023. Subsequently, user tests with Axia were carried out in the period between 15 July 2023 and 31 October 2023 with the major goals to obtain structured user feedback as well as to collect data on the performance and safety of the app. To use Axia, it was first necessary to download the app from the app store (either Google Play Store or Apple App Store). The testers then created a user account and received an activation code from the manufacturer, which activated the app for a limited period starting from the time when the code was initially entered into the app.
All participants who had access to the app for at least ten days were invited to complete a mixed-method 38-question survey on the app in German language at the end of their usage period. The post-market survey was created using the tool "LamaPoll" (lamapoll.de, Software-As-A-Service) and the data were collected and analysed anonymously (14). The survey asked about various aspects of usage and user experience. It mainly consisted of nominally or ordinally scaled items (mainly dichotomous items, numerical rating scales (NRS), or likelihood scales). The translated questionnaire is presented in the supplemental file.

**Ethics Approval**

All participants provided informed consent to take part in the survey and the study was submitted to the ethics committee of the Medical Faculty of the University of Wuerzburg (Application 2023112302). The ethics committee considered the study to be part of the quality management process. Therefore, the study required no further ethical approval.

**Subjects and Recruitment**

Potential participants were informed about the app via DVMB's own social media channels and the ankylosing spondylitis journal 173 (June 2023) published by the DVMB. Interested persons were invited to contact the manufacturer via email. Approximately 250 individuals responded. Since the manufacturer planned to include only about 50 axSpA-patients in this quality management process, 54 axSpA-patients were selected chronologically from all enquiries and invited to a short video call, during which their app access was explained (activation by entry of an activation code) and any remaining questions were clarified. Participants were each given test access for at least 10 days, with the majority having access to the app for exactly 10 days (n[10d] = 50, n[90d] = 3, n[30d] = 1).

During the set-up video call, nine of the 54 included people stated that they did not wish to take part in the announced survey. During their usage period, three of the remaining 45 persons reported that they had stopped using the app for other, non-axSpA or app-related medical reasons. They were excluded, just like one other person who stated that he did not wish to provide feedback. Finally, one more user was excluded since he was unable to use the app for technical reasons. Thus, a link to the survey was sent to 40 test users. Out of these, 37 completed the survey and were included in the following analysis (Fig. 3 presents the CONSORT flow diagram of the study).

**Analysis**

LamaPoll provided an Excel file with the anonymous raw data. Then, Excel 2016 was further used for the primary analysis of response frequencies of each item. For correlation studies, SPSS Version 27 was used. Because mainly ordinal-scaled variables were included in the analysis we used the Spearman correlation test. Results were presented as Spearman’s ρ with a two-sided significance test. When p < 0.05 results were interpreted as significant, and correlation was interpreted. In accordance with Cohen, ρ > 0.1 was interpreted as low/ weak correlation, ρ > 0.3 as medium, and ρ > 0.5 as large correlation (15). Continuous values were tested for normal distribution by using the Shapiro-Wilk test via GraphPad Prism, Version 5. Because normal distribution could not be determined, medians with interquartile ranges (IQR) were calculated, and the Mann-Whitney U test was used for analyzing differences. When p < 0.05, differences were interpreted as significant.

**Results**

**Descriptive Information**

**General information**

All 37 participants (female = 25, male = 12) who completed the survey had downloaded and activated Axia and set up an individual user account. These people were included in the final analysis (see CONSORT diagram, Fig. 3). They were not given any specifications regarding the frequency of use of the app, nor was their usage behaviour technically checked or tracked after initial activation. There were no reminder emails for users, thus, they were free to use or not to use Axia just as they wanted to.

**User characteristics**

The median age was 50–59 years (IQR 10 years) and the median time since disease onset was 11–20 years (IQR 25 years). On an NRS scale (0–10), the median disease activity/ patient global assessment (PGA) – based on the last four weeks and rated by the participants – was 5 (IQR 3). The median disease-specific pain (NRS pain) based on the past four weeks was also 5 (IQR 3). The NRS pain correlated well with the PGA (ρ = 0.678, p < 0.001). Age as well as disease duration did not correlate with PGA or the NRS pain, but age correlated well with disease duration (ρ = 0.642, p < 0.001).

**Evaluation of the user tests**

**Axia in general**

All users (n = 37) could orientate well in Axia and had no issues using all relevant functions. On an NRS (0–10) to express Axia utility, the design and attractiveness were rated with a median of 5 (IQR 2) on an NRS scale (0–10). In total, 75.7% (n = 28) would rate the app with 5 of 5 stars and 24.3% (n = 9) with 4 of 5 stars (median 5 stars, IQR 1). No subject rated Axia worse than 4 stars. 94.6% (n = 35) stated that Axia will permanently improve their disease management. 78.4% (n = 29) stated that they would be willing to pay for the continued use of Axia. In correlation analysis, the number of awarded
stars correlated well with the NRS design ($\rho = 0.35$, $p = 0.33$) and the satisfaction with Axia in total ($\rho = 0.614$, $p = 0.001$). Figure 4 summarizes the main results of the user tests.

**Academy Function**

Regarding the patient-educational function, 83.8% ($n = 31$) have used the Academy function at least once, while 16.2% ($n = 6$) have never used it. Of those who used the academy, 93.6% ($n = 29$) are convinced that the academy helped them to improve their disease-specific knowledge, while almost all of them (96.8%, $n = 30$) think that the academy will help them in coping with axSpA. On a scale from 1 to 5 (1 = very bad, 2 = bad, 3 = neutral, 4 = good, 5 = very good), all rated the selection of the covered topics as good ($n = 14, 45.2\%) or even very good ($n = 17, 54.8\%).

**Exercise Program**

97.3% ($n = 36$) answered that they benefited from the selected exercise program and 91.9% ($n = 34$) agreed that Axia helped them to integrate more exercises into their daily activities. 97.3% ($n = 36$) believed that Axia will keep them training. Before using Axia, 46.0% ($n = 17$) had not performed HbE and with Axia, 97.3% ($n = 36$) performed HbE, thus, Axia increased the total number of new HbE performers by 80% ($n = 16$ subjects started new HbE). However, Axia also increased the quantitative level of HbE (Fig. 5): The median of days per week of HbE was 1 (IQR 4) before Axia and increased significantly with the use of Axia to 6 days per week (IQR 2.5, $p < 0.0001$). Remarkably, even in the subgroup of participants who had already been performing HbE, the median of days per week performing HbE increased significantly by using Axia (before Axia 4 days per week, IQR 3.75, with Axia 6 days per week, IQR 2.75, $p = 0.011$). In line with this, 56.8% ($n = 21$) answered that they could imagine to train daily with Axia, 37.8% ($n = 14$) would still exercise several times a week, while only 5.4% ($n = 2$) would use Axia only once a week or more seldom in future. 100% ($n = 37$) believe that Axia will help them to achieve or maintain a high level of exercise. A direct correlation was found between the initial NRS pain and the grade of HbE with Axia ($\rho = 0.437$, $p = 0.007$) as well as the initial PGA and the grade of HbE with Axia ($\rho = 0.409$, $p = 0.012$).

**Subjective disease improvement by using Axia**

While 35.1% ($n = 13$) did not notice an improvement in the range of movement, 56.8% ($n = 21$) felt a mild improvement and 8.1% ($n = 3$) even a great improvement, despite the short period of use. Remarkably, no subject stated a worsening of the range of movement. 97.3% ($n = 36$) believe that Axia would improve their flexibility with prolonged use. In correlation analysis, improvement of range of motion correlated well with the grade of HbE with Axia ($\rho = 0.432$, $p = 0.008$).

Regarding pain, 43.2% ($n = 16$) remarked mild pain relief while 48.7% ($n = 18$) had no improvement of their pain. The residual 8.1% had no pain at all. 89.2% ($n = 33$) think that Axia can help to decrease their level of pain with prolonged use. No significant correlation was found between the grade of pain relief and the grade of HbE with Axia. Interestingly, a direct correlation was found between the initial NRS pain and the subjective pain relief by using Axia ($\rho = 0.463$, $p = 0.006$).

**Documentation Function**

Regarding documentation functions, 100% ($n = 37$) think that Axia is suitable for adequate documentation of sports activities and 86.5% ($n = 32$) stated that Axia is also suitable for documentation of disease-specific symptoms.

**Recommendation to other patients**

All of the users would recommend Axia to other patients and 94.6% ($n = 35$) even stated that they were very likely to recommend the app to other patients.

**Discussion**

**Principal findings**

In this article, the DTx Axia is presented as well as the first data from a patient survey indicating that Axia might be effective for axSpA-patients. Besides technical and software issues we also analyzed the results of the survey's questionnaire: We found that Axia significantly improved the level of HbE independent of the initial level of HbE during the user tests. The fact that DTx can improve patients' daily activity was also shown before (9) (16) (17). Thus, Axia clearly fulfilled one of its primary purposes to motivate participants to HbE. Remarkable in this context, we discovered that the NRS pain as well as the PGA correlated well with the grade of performance of HbE with Axia. This is not surprising, because pain as well as disease activity might be crucial motivating factors for performing disease-specific exercise aiming to improve these impairments in the future. The fact that the majority of the users were willing to exercise with Axia on a daily basis for the most part of their test period might be explained by its appealing design as well as its intuitive use: Axia achieved good user satisfaction, with a median of 5 out of 5 stars awarded to Axia. All users would recommend Axia to others, and almost 78% would even use Axia at their own expense if Axia would not be reimbursed by their health insurance. We believe that we have achieved this high contentment by developing Axia in close cooperation with the axSpA-patients and their patient self-help association DVMB.

**Comparison with other German-language DTx for rheumatic disease**

Developing German-language DTx for German-speaking patients of rheumatic diseases, especially axSpA, is not a completely new concept: While the majority of already existing rheumatic DTx offer mainly documentary, consulting or patient-educative functions (Pain companion, MyTherapy, AxSpALive, RheumaLive, RheumaBuddy) only a small number of DTx provide direct therapeutic interventions (18). Here, especially the DTx Rheuma-Auszeit (Rheuma-Liga e.V., Bonn), YogiTherapy (University of Erlangen and University Hospital of Erlangen, Erlangen), and reclait (Gaia, Hamburg and Chugai, Frankfurt/Main) have to be
mentioned (16) (18) (19) (20). While reclarit offers a behavioral therapeutic intervention aiming at improving the mental quality of life of patients with rheumatoid arthritis, Rheuma-Auszeit and YogiTherapy also provide exercises for HbE and can therefore be regarded as direct comparison products (16) (19) (20). Rheuma-Auszeit, developed by the German self-help group Rheuma-Liga, is no medical device according to the European MDR and is not specific for axSpA compared to Axia (20). Nevertheless, Rheuma-Auszeit achieved good results in the uMARS in a validation study with a mixed group of patients suffering from different rheumatic diseases (21). Furthermore, the license holders of Rheuma-Auszeit (Rheuma-Liga) are not considering to further developing Rheuma-Auszeit into a medical device or even a reimbursed DHA at the moment (according to the information on their homepage (20)). YogiTherapy was developed by the University of Erlangen and offers a Yoga-based training specific for axSpA-patients (16). According to the publication of their user tests, the developers initially planned to develop YogiTherapy as a medical device (16). So far, YogiTherapy has not yet been certified as a medical device to the best of our knowledge and is now offered as free ware in app stores. YogiTherapy showed good results in their user test regarding attractiveness and stimulation, but these results should be interpreted in the knowledge of the low number of participating patients (n = 5) and rheumatologists (n = 5) in this first survey (16). Furthermore, YogiTherapy mainly offers a Yoga-based exercise form (16). In conclusion, there is currently no DTx on the German-speaking market similar to Axia which is both a medical device and offers a universal axSpA-specific exercise program.

How Axia anticipates the challenges for DHA in rheumatic diseases

Only one study has investigated the usage of German-language DHA in rheumatic diseases in the real-world so far and revealed that the main problems of DHAs are on the one hand the onboarding of patients to the DTx and on the other hand to achieve permanent adherence to the DTx (9). Axia was therefore designed and developed in close collaboration with the affected patients to better address these issues: In our survey, Axia received excellent ratings for its intuitiveness and operability which is crucial for onboarding users. Additionally, all volunteers in our study were able to download and activate Axia successfully. Only one user stopped using Axia later due to technical issues. Thus, we achieved a successful onboarding rate of 100%, which was as double as high as the rate of 46% reported from the study conducted by Labinsky et al with a similar case number as our survey (n = 39) (9). Our data might of course be confounded by the fact that our participants might have been higher motivated than the subjects in the above-mentioned trial and the onboarding process was further supported by video-calls. Alternatively, Axia might be more attractive for axSpA-patients than the non-rheumatic DHAs which were prescribed by Labinsky and colleagues (9). Besides the onboarding process, the even more considerable issue of mobile health products is their low adherence rate (9) (13): Only almost half of the successfully onboarded participants (55%) in the Labinsky trial further used their DHA after the installing process (9). The phenomenon of fast attrition is also well-known in the whole digital world besides mobile health products (13). Strikingly, all of our participants in the survey maintained their engagement with Axia and showed an almost daily use of Axia expressed as the median HbE rate of 6 days/week which overwhelms the adherence rate reported by Labinsky et al (9). We believe that this might at least partly be caused by the gamification factor and feedback mechanisms of Axia leading to its good ratings for design as well as for entertainment. Of course, our observational period of almost two weeks was very short compared to the three months in the Labinsky trial (9). Nevertheless, a considerable proportion of users in studies stop using their apps and mobile health products shortly after beginning to use them, which is comparable to our observational period (9) (13). We were unable to observe this high attrition rate, as only four users in our study stopped using Axia. In line with this, 97% of the participants of the survey stated that they would use Axia permanently in future. Whether Axia permanently leads to such high adherence rates in the long term must be examined in further studies with longer observation periods.

Strength and limitations

The findings of our study must be interpreted with caution due to its several limitations:

1. Small Sample Size: The study had a limited sample size of 37 participants, and all data was self-reported by patients.
2. Questionnaire Selection: We avoided using extensive but validated questionnaires like uMARS or BASDAI to reduce the burden on participants. These will be employed in future randomized controlled trials.
3. Volunteer Participants: All participants were volunteers from the German self-help association DVMB, potentially representing a highly motivated subgroup more likely to adopt new therapies than the general axSpA patient population in Germany. To avoid a selection bias, we did not pick the most suitable or motivated participants but recruited chronologically by the time of the email receiving.
4. Unverified User Statements: We did not verify the accuracy of users’ statements about their frequency of app usage.
5. High Screen Failure and Dropout Rates: It remains unclear why a high proportion (nine of 54/17%) of the screened subjects did not want to take part in the survey. Eight of 45 enrolled subjects (18%) dropped out due to several reasons. Due to the design, the analysis could only be carried out with the per protocol approach. It is possible that only the most motivated and fittest subjects completed the study, with possible distortion of the results.
6. Preliminary Data: Despite these limitations, this study provides initial insights into the use, functionality, and user satisfaction of a new digital medical device. It highlights a novel form of digital exercise intervention highly sought after by German axSpA patients (7).

These factors underline the need for further research with a broader and more diverse participant base and longer observation periods to validate these initial findings.

Conclusions and Future Steps

In conclusion, Axia is a new CE-marked medical device offering a digital form of exercise intervention for patients with axSpA. Axia achieved high user satisfaction and recommendation rates in user testing. Additionally, it helped users to increase their HbE frequency, regardless of prior engagement in HbE activities. The next phase involves conducting two large randomized controlled interventional trials with axSpA patients to evaluate Axia’s efficacy over time. These studies are scheduled to begin in February 2024, aiming to establish the first DHA for axSpA in the German healthcare system and to provide a new, validated method of exercise intervention.

Abbreviations
Declarations

Ethics approval and consent to participate

All participants provided informed consent to take part in the survey and the study was submitted to the ethics committee of the Medical Faculty of the University of Wuerzburg (Application 2023112302). The ethics committee considered the study to be part of the quality management process. Therefore, the study required no further ethical approval.

Consent for publication

All participants provided informed consent to publication of the study’s results.

Availability of data and materials

We provided a supplemental file. Further information can be requested from the authors.

Competing interests

PPS received speaker’s fees and travel grants from Janssen-Cilag Galapagos, Eli Lilly, Boehringer/Ingelheim and AbbVie (less than $10,000 each) as well as research funding from Chugai (25000$).

MLM: Chief Executive Officer of Applimeda, Co-Founder and shareholder of Applimeda GmbH

TH: Chief Regulatory & Medical Officer of Applimeda, Co-Founder and shareholder of Applimeda GmbH

JK: PRRC of Applimeda

HL received travel grants from UCB, Boehringer Ingelheim, Pfizer, and Abbvie as well as compensations for consulting activity from Pfizer and for lecturing activities from Janssen.

Anna Fleischer: none declared.

KSL: none declared.

PP: non declared

MG received travel grants, compensation for advisory boards or speaker’s fees from AbbVie, Chugai, Eli Lilly, Hexal, Janssen, Novartis, Pfizer, Takeda.

RL: Chief Technology Officer of Applimeda, Co-Founder and shareholder of Applimeda GmbH.

AS: none declared.

LH: Former Chief Executive Officer of DVMB.

ES: Chief Executive Officer of DVMB.

BS: none declared.
MF received speaker's fees, travel grants or compensation for board memberships from AbbVie, Novartis, Janssen, and Eli Lilly.

MS received speaker's fees, travel grants, research funding, or compensation for consultancies or board memberships from AbbVie, Actelion, AstraZeneca, BMS, Boehringer/Ingelheim, Celgene, Chugai/Roche, Eli Lilly, Genzyme, Gilead, Hexal/Sandoz, Janssen-Cilag, MSD, Novartis, Pfizer, Sanofi Pasteur, Takeda (Shire), UCB (less than $ 10,000 each).

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**Authors' contributions**

PPS, MLM, and TH conceived the study. MLM and TH conducted the survey. PPS, MLM, and TH interpreted the results. Drafting: PPS, MLM, TH, and MS. All authors contributed to the article and approved the submitted version. All authors discussed the results and contributed to the final manuscript. The final manuscript was approved by all authors.

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**References**


**Figures**

![User interface and dashboard of Axia](image.png)

**Figure 1**

**User interface and dashboard of Axia**

In the middle of the screen, the main elements of gamification are presented: On the left side, there is the mascot "Bechto" with a green flag expressing positive feedback to the user for his high adherence in exercise therapy. On the right side, the “points tank” is shown in the form of a speedometer. Points can be collected by performing disease-specific exercises, sports, or educational lessons. In the middle of the screen, one button for starting an exercise routine and one for starting an exercise program are visible. At the bottom of the screen, you find a menu to navigate between the home screen, acute pain section, educational (Academy), and symptom tracking functions.
Axia includes over 250 different exercise videos. All of them were professionally filmed with multiple camera angles to present the correct way of exercise execution. Before starting the exercise, an initial instructional video with detailed explanations is presented to the user before starting to perform the exercise itself. A professional narrator guides the patient through the instruction as well as training to ensure correct exercise execution. Experienced users can skip the instructional video and directly perform the exercises.

**Figure 3**

CONSORT flow diagram of the study

All recruited volunteers were able to download Axia from the App Stores and onboard the App on their mobile end device. Nine participants refused to take part in the survey, from the enrolled subject, four had to be excluded due to non-axSpA-specific medical or technical issues. One participant withdrew his consent to take part in the survey, and three more subjects were lost of follow up in the survey because they did not complete the questionnaire.
Increase in Home-based Exercise
Before Axia, patients performed HbE at a median of 1 d/week, with Axia at a median of 6 d/week (p=0.001). In those already performing HbE, Axia led to an increase from a median of 4 d/week to 6 d/week (p=0.011).

High efficacy perceived by patients
94.6% believe that Axia will permanently improve their disease management.

Increase in disease-specific knowledge
93.6% of users gained new knowledge to help them manage their condition in the future.

Median rating by patients: 5/5 ⭐
Axia was highly rated by patients, with 75.7% giving it a perfect 5-star rating and 24.3% giving it 4 stars. All users would recommend Axia to other patients.

Reduction in pain levels
Despite the short period of use, 43.2% reported a reduction in pain levels after using Axia.

Improvement in range of motion
64.9% of participants experienced a significant improvement in range of motion.

Figure 4
Overview of the user test results of Axia
This figure summarizes the main findings of the user tests and emphasizes that Axia received great ratings by the testers.

Figure 5
Change of Home-based exercise by the use of Axia
The use of Axia significantly improved the frequency of home-based exercised (HbE) compared to the level of the last 4 weeks before start of the study. Only 54.0% (n=20) participants performed regular home-based exercise before the study. Even in this subgroup, the frequency of HbE increased significantly. ⭐ P=.011; ⭐⭐⭐ P<0.001.

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryFile.docx