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First experience of a hemophilia monitoring platform: florio HAEMO

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Abstract

Background: florio HAEMO is a new hemophilia treatment monitoring application consisting of a patient smartphone application (app) and a web-based dashboard for healthcare professionals, providing several novel features, including activity tracking, wearable connectivity, kids and caregiver mode, and real-time pharmacokinetic factor level estimation.

Objectives: To assess intuitiveness, ease-of-use, and patient preference of florio HAEMO in Central Europe using a cross-sectional survey.

Methods: This survey was conducted in six Central European countries between 9 December 2020 and 24 May 2021. The online questionnaire included 17 questions about overall satisfaction, ease-of-use, intuitiveness, and patient preference. Adults or children with hemophilia on regular prophylaxis and using the florio HAEMO app

for a minimum of 1 week were invited to complete the online questionnaire by their treating physician.

Results: Sixty-six participants took part in the survey. The median duration for all respondents using the florio HAEMO app was 3 to 4 weeks. Overall, 89.4% of users reported being very satisfied or rather satisfied after using florio HAEMO. Of the 23 respondents who had switched from another hemophilia app, 87.0% indicated that they strongly preferred or preferred using florio HAEMO. Most florio HAEMO users reported that the app was very easy or rather easy to use (97.0%) and intuitive (94.0%). florio HAEMO had a positive impact on daily living, with 78.8% of users reporting that the app was very important or rather important to them.

Conclusions: This survey suggests that florio HAEMO is an easy-to-use and intuitive app to assist self-management of home prophylaxis.

KEYWORDS
hemophilia, patient preference, pharmacokinetics, telemedicine

Essentials

- florio® HAEMO is a new hemophilia monitoring platform for adults, children and caregivers.
- A survey in Central Europe assessed intuitiveness, ease-of-use and preference of florio HAEMO.
- Most respondents reported florio HAEMO as intuitive, easy to use and preferred.
- The survey suggests that florio HAEMO can support families with home prophylaxis for hemophilia.

1 | INTRODUCTION

Today, prophylactic self-infusion of factor concentrate in the home setting is the standard of care for most people with hemophilia.[1] Patients or caregivers have traditionally written a paper diary to help track home infusions and bleeding episodes, which the treating clinician checks during a biannual clinic visit.[2] Poor adherence and delays in addressing medication issues are inherent challenges with paper diaries.[2] Electronic documentation tools such as handheld devices have been developed over the years to help address these issues, which enable the treating physician to more closely monitor the patient, leading to better care outcomes, faster resolution of medication issues, and improved adherence.[2-5] More recent studies have shown that mobile Health (mHealth or telemedicine) applications (apps) that collect data through mobile/wearable devices to trigger real-time interventions have greater potential to optimize care of people with hemophilia.[5]

Several smartphone apps offering a secure patient recording system are available to help people with hemophilia log infusions of factor replacement products, record bleeds, and track remaining stock (e.g., HaemoAssist 2, Haemtrack, Smart Medication, myPK-FiT®, myWAPPS, MicroHealth, myABDR, myCBDR) and, the most recently introduced app, florio HAEMO.[3,5-11] We report the first user experience of florio HAEMO, based on the results of a cross-sectional survey designed to assess the app's intuitiveness, ease-of-use, and patient preference for people with hemophilia and their caregivers across six Central European countries.

1.1 | florio HAEMO (and florio HAEMO Kids)

florio HAEMO (Florio GmbH, Munich, Germany; https://florio-haemo.com/) is a new hemophilia monitoring application consisting of a patient smartphone app and a web-based dashboard for healthcare professionals. The florio HAEMO patient app provides several novel features compared with some existing apps, including the ability to report on physical activities, pain in the absence of bleeds, upload photographs and information related to bleeds and queries, monitor wellbeing, plus an option to obtain data from a wearable device to enhance activity tracking. In contrast to some available apps, florio HAEMO is not product-specific and can conveniently be used with any factor replacement product. In addition, a companion app for children (florio HAEMO Kids) that can be used in conjunction with the parent/caregiver mode of the florio HAEMO app has been developed. florio HAEMO Kids is designed to enable children to learn the importance of prophylactic treatment interactively and offers age-appropriate features to help children keep track of prophylaxis and progress.

Population pharmacokinetic (PK)-powered real-time factor level estimations are important to help people with hemophilia avoid unexpected bleeds and guide their daily activities.[12,13] Bayesian analysis is an accepted methodology for PK-guided, personalized treatment plans and fundamental in florio HAEMO for hemophilia A or B patients to estimate real-time factor levels.[13-15] florio HAEMO uses McMaster PopPK, which is CE-marked as an in vitro diagnostic (IVD) device class I in accordance with the EU IVD Directive.[16] McMaster

PopPK is a centralized, dedicated, actively-moderated database that allows participating hemophilia centers to securely input factor VIII/IX plasma levels from sparse samples and return individual patient PK estimates.[16] Once prophylactic infusions are logged, the florio HAEMO app displays the new factor level estimates and updates the remaining home stock.

For healthcare providers (HCPs), the florio HAEMO browser-based dashboard integrates real-time data exchange with the florio HAEMO patient app, providing individual patient and HCP-level access to patient-reported data, activity tracking, and automatically calculated variables such as annualized bleed rates, adherence, and time factor levels above 15 IU/dl (15%). HCPs can therefore download a preformatted report for each of their patients. Thus, florio HAEMO allows people with either hemophilia A or B on prophylaxis with factor concentrates to share personal disease-related information with their physician/HCP in real-time, to support individualized care, and provide meaningful consultation between patients and physicians.

2 | METHODS

2.1 | Study design

This cross-sectional survey was conducted in Croatia, Czech Republic, Hungary, Poland, Slovakia, and Slovenia. Two online patient satisfaction questionnaires comprising a baseline survey and a follow-up survey were designed to be completed 6 months apart. The baseline survey questionnaire consisted of 17 questions about overall satisfaction, ease of use, intuitiveness, and demographic data such as age and education level of the user using a 5-point Likert scale and open-ended questions. People with hemophilia and parents/caregivers of children with hemophilia completed the baseline survey at least 1 week after the start of using the florio HAEMO app. Results from the follow-up survey, focusing on wearable functionality and long-term adherence of florio HAEMO, will be reported when they are available after 24 to 26 weeks of usage.

The survey was designed by experts from the field of hemophilia treatment. The two questionnaires were developed in English and translated into each local language. All participants provided informed consent. The online survey platform (Typeform) was administered by Seesame s.r.o (Bratislava, Slovakia). Responses were collected and analyzed by Seesame s.r.o in compliance with EU General Data Protection Regulation 2016/679, local legislations, and Ethics Committee approval. No internet protocol addresses or other identifiable information were stored. The Central European florio HAEMO expert panel interpreted the anonymized results.

2.2 | Participants

Adults and children with either hemophilia A or B of any severity on regular prophylaxis with any factor concentrate (e.g.,

plasma-derived, standard half-life[5] recombinant, extended half-life recombinant) could participate in this survey. A total of 106 people with hemophilia or caregivers of people with hemophilia using florio HAEMO in Central Europe were invited to complete the online survey via an electronic link sent by the treating physician. Respondents (people with hemophilia and caregivers of people with hemophilia) were divided into five groups according to age: group 1: parent/caregiver of a person with hemophilia aged 6 years or younger; group 2: parent/caregiver of a person with hemophilia aged 7–12 years; group 3: either a person with hemophilia or parent/caregiver of a person with hemophilia aged 13–25 years; group 4: person with hemophilia aged 26–49 years; and group 5: person with hemophilia aged 50 years or older. All participants had a population PK analysis performed at the start of using the florio HAEMO application. Survey participants were enrolled over 5 months between 9 December 2020 and 24 May 2021. Participants who completed the baseline survey agreed to continue using florio HAEMO and complete the follow-up survey.

2.3 | Statistical analysis

Results from this survey are reported using descriptive statistics. No formal statistical testing was performed.

3 | RESULTS

3.1 | Survey participants

Sixty-six respondents ($n = 40$ people with hemophilia and $n = 26$ caregivers/parents of people with hemophilia) using florio HAEMO had completed the baseline survey (data cut-off 24th May 2021). The respondents represented people with either hemophilia A ($n = 57$; 86.4%) or hemophilia B ($n = 9$; 13.6%). Table 1 shows that most of the respondents (62.1%) were people with hemophilia or caregivers/parents of people with hemophilia aged between 13 and 49 years. Standard half-life or extended half-life recombinant FVIII products were the most frequently administered type of prophylaxis (30.3% and 48.5%, respectively). The median duration using the florio HAEMO app for all respondents before completing the baseline survey was 3–4 weeks (range 1 to ≥7 weeks). Notably, 22 of the 66 respondents (33.3%) had used the florio HAEMO app for at least 7 weeks before completing the baseline survey. More than one-third of respondents (34.8%) had previously used another hemophilia monitoring app before switching to florio HAEMO. Twelve patients (18.2%) had switched from using myWAPPS, six (9%) had switched from using myPKFit, three switched from using MicroHealth, and other respondents did not specify which hemophilia monitoring device they had previously used. An Android operating system was used in conjunction with the florio HAEMO app by most respondents (77.3%) (Table 1).

TABLE 1 Demographics and characteristics of respondents

	Respondents (N = 66) n (%)
Respondent	
Person with hemophilia aged 13 years or older	40 (60.6%)
Parent/caregiver of a person with hemophilia	26 (39.4%)
Age	
Group 1: Parent/caregiver of a person with hemophilia aged ≤6 years	8 (12.1%)
Group 2: Parent/caregiver of a person with hemophilia aged 7–12 years	15 (22.7%)
Group 3: Either a person with hemophilia or parent/caregiver of a person with hemophilia aged 13–25 years	19 (28.8%)
Group 4: Person with hemophilia aged 26–49 years	22 (33.3%)
Group 5: Person with hemophilia aged ≥50 years	2 (3.0%)
Country of respondent	
Croatia	12 (18.2%)
Czech Republic	26 (39.4%)
Hungary	9 (13.6%)
Poland	6 (9.1%)
Slovakia	10 (15.2%)
Slovenia	3 (4.5%)
Primary user of florio HAEMO app[a]	
Yes	62 (93.9%)
No	4 (6.1%)
Education level of the respondent (person with hemophilia aged 13 years or older or parent/caregiver of a person with hemophilia)	
Not yet finished secondary school	16 (24.2%)
Current student at college/university	3 (4.5%)
Currently in further education	12 (18.2%)
Degree (university or college)	22 (33.3%)
Other (finished secondary school but did not enter further education)	13 (19.7%)
Type of factor concentrate	
pd-FVIII	5 (7.6%)
SHL-FVIII	20 (30.3%)
EHL-FVIII	32 (48.5%)
pd-FIX	1 (1.5%)
SHL-FIX	4 (6.1%)
EHL-FIX	4 (6.1%)
Duration using florio HAEMO before completion of the baseline survey	
1–2 weeks	13 (19.7%)
3–4 weeks	24 (36.4%)
5–6 weeks	7 (10.6%)
≥7 weeks	22 (33.3%)

TABLE 1 (Continued)

	Respondents (N = 66) n (%)
Operating system used for florio HAEMO	
iOS	15 (22.7%)
Android	51 (77.3%)
Previous use of ≥1 hemophilia monitoring app	
Yes	23 (34.8%)
No	43 (65.2%)

Abbreviations: EHL, extended half-life recombinant; FIX, clotting factor IX; FVIII, clotting factor VIII; iOS, internet operating system; pd, plasma-derived; SHL, standard half-life recombinant.

[a]florio HAEMO is installed on the respondent's smartphone.

3.2 | Overall user satisfaction, compliance, and patient preference

The majority of respondents (89.4%) were very satisfied or rather satisfied after using the florio HAEMO app (Figure 1). Since starting to use florio HAEMO, 52 (78.8%) respondents indicated that they managed to enter all relevant data for all infusions, with only 12 respondents (18.2%) reporting that they had skipped data entry for at least one infusion. Of the 11 (16.7%) people with hemophilia on prophylaxis who had experienced pain, seven (63.6%) reported using the florio HAEMO app to enter pain level compared with only four (36.4%) who did not enter their pain level when it was present at least once.

The most frequently used app function indicated by respondents was monitoring factor levels (89.4% of respondents) and the least frequently used function was discussing data with my doctor (3.0% of respondents) (Figure 2).

Of the 23 respondents who had previously used another hemophilia monitoring app before using florio HAEMO, 20 (87.0%) indicated that they strongly preferred or preferred florio HAEMO and two (8.7%) stated they had no preference; one respondent who had previously used another app stated that they did not find the question applicable.

3.3 | Ease of use and intuitiveness

florio HAEMO users were asked to assess how easy it was to use the app and how intuitive the app features were. For most users (97.0%), florio HAEMO is very easy or rather easy to use (Figure 3A). Similarly, 62 of the 66 respondents (93.9%) indicated that the app is very intuitive or rather intuitive to use (Figure 3B). Forty-seven respondents (71.2%) did not experience any difficulties using the app (Figure 4).

3.4 | Impact of florio HAEMO on daily living

When asked about how essential the florio HAEMO app was in bringing more certainty to daily life for people with hemophilia or

FIGURE 1 Overall satisfaction of respondents using florio HAEMO (N = 66)
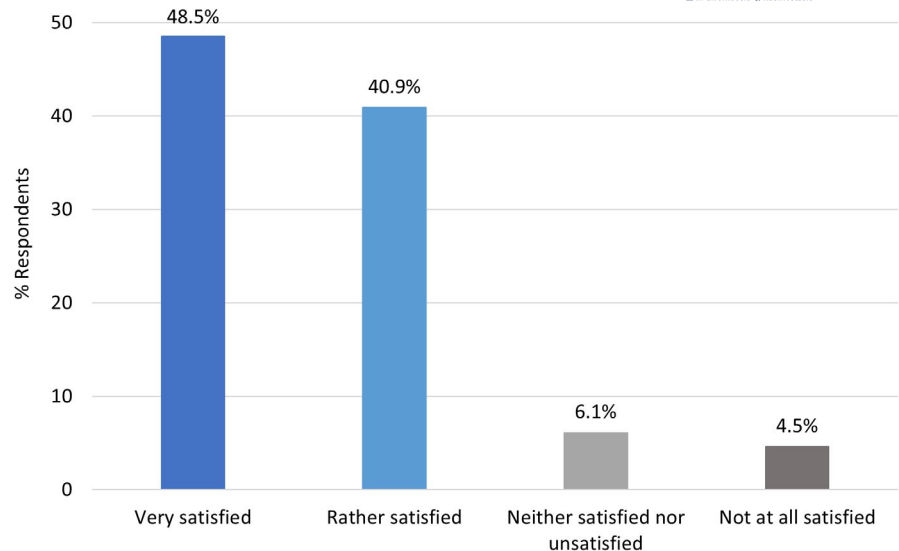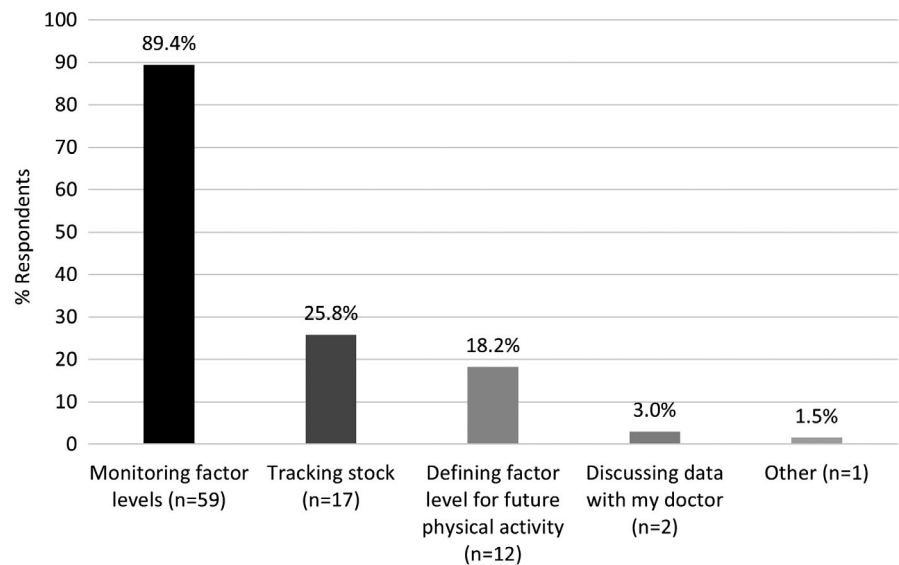

FIGURE 2 Most frequently used florio HAEMO function (N = 66). Note that respondents could provide more than one answer to the multiple-choice questions

their parents/caregivers, 78.8% of users responded that the app was very important or rather important to them (Figure 5). Approximately one-half of all respondents (45.5%) expressed an interest in testing a wearable device to increase the precision capabilities of florio HAEMO and support daily physical activities.

3.5 | Subgroup analysis by age and florio HAEMO experience

To ascertain whether age (≤12 years or ≥13 years) and/or duration of florio HAEMO app use before completion of baseline survey (1–4 weeks or ≥5 weeks) affected results, the responses for eight relevant questions were further analyzed (Appendix S1). A small number of respondents reported uncertainty on how to start using the app or difficulties using the app on the rare occasion the application did not work (e.g., losing connectivity to server after changing treatment plan) (Figure S5). There was a slight trend that people with hemophilia using the app were more satisfied than caregivers/

parents of people with hemophilia who used the app (Figure S2). The longer the app was used, the more time was allowed for clinical review appointments, and, therefore, respondents were more likely to discuss results with a physician (Figure S6).

4 | DISCUSSION

Our Central European patient baseline survey suggests that users find florio HAEMO easy to use in Android and iOS (Apple Inc.) operating systems, which may facilitate adherence in reporting data in the app. Overall, most respondents indicated that they were satisfied with the mobile app and that it brought more certainty to daily activities for people with hemophilia and caregivers/parents of people with hemophilia.

In hemophilia, where long-term adherence to prophylaxis is critical, the patient-physician relationship is long term and healthcare resource utilization is high, patient experience and satisfaction are very important.[17] Salisbury et al.[18] investigated how telemedicine, a
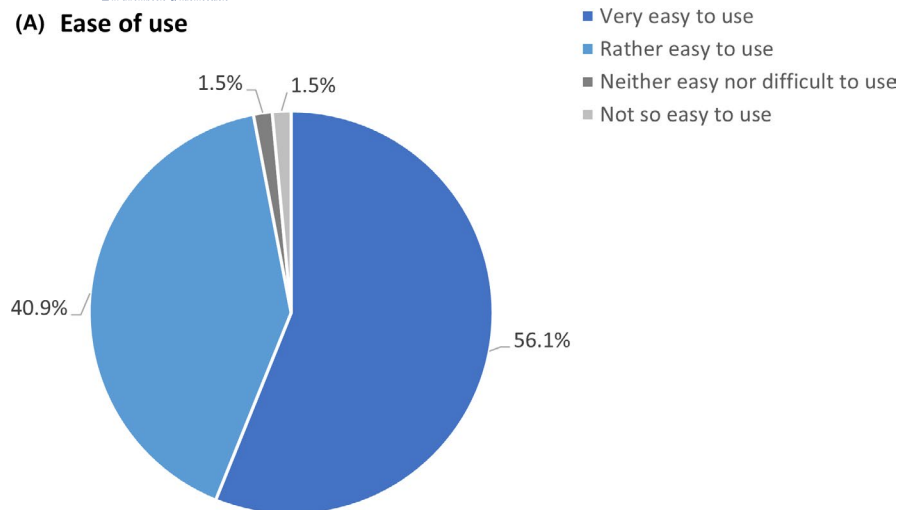
(A) Ease of use

- Very easy to use
- Rather easy to use
- Neither easy nor difficult to use
- Not so easy to use

1.5% 1.5%
40.9%
56.1%

(B) Intuitiveness

- Very intuitive**
- Rather intuitive
- Neither intuitive nor unintuitive
- Rather unintuitive
- Not intuitive*

1.5% 1.5%
3.0%
37.9%
56.1%

FIGURE 3 Ease of use and intuitiveness of florio HAEMO (N = 66). *Not intuitive, i.e., help is needed on a regular basis. **Very intuitive to use, i.e., I learned quickly
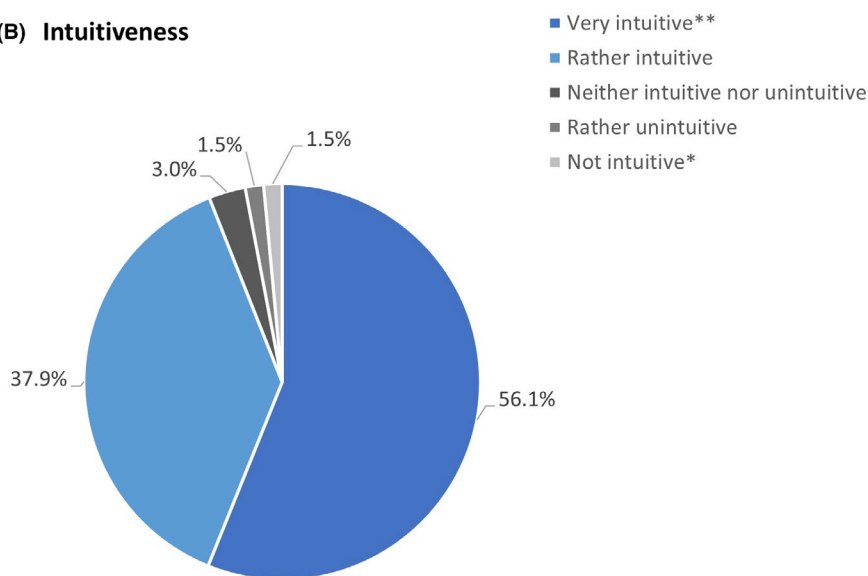
broader term for healthcare using modern technology, may provide a better experience for patients with chronic health conditions. This study revealed that for telemedicine apps to be effective, they need to be accessible, easy to use, and integrated into everyday routines by patients and professionals.[18] In the baseline survey, most users found florio HAEMO easy to use and were satisfied overall with their experience.

Although mobility problems and pain may be associated with advanced joint disease, uncertainty during daily activities and unexpected bleeds are rather individual, poorly predicted, and considerably disruptive in the lives of people with hemophilia. Indeed, qualitative research of 51 people with hemophilia across five European countries highlighted that uncertainty in daily life is a broadly accepted limitation, necessitating a personalized approach to care.[19] The rationale for integrating the florio HAEMO app into daily life is supported by the fact that most respondents in our baseline survey were compliant entering their infusion data and reported that the app brought more certainty to everyday life for themselves or the child with hemophilia they care for. In our survey, monitoring factor concentrate

levels was the most frequently used florio HAEMO app function. Tailoring prophylaxis for people with hemophilia using population pharmacokinetic-assisted monitoring may improve treatment efficiency while also increasing certainty in everyday life.[20]

Personal hemophilia monitoring software such as florio HAEMO has the potential to increase the effectiveness of healthcare delivery by improving patient/physician discussions, possibly reducing the need for hospital visits, reducing complications and/or hospitalizations and improving patient adherence and outcomes, which can free up healthcare resources to treat additional patients.[21] The main advantage of such technical solutions is the ability to integrate relevant data in one platform.

The second Central European patient survey will evaluate the impact of obtaining data in the florio HAEMO app from a wearable watch to monitor physical activity levels. After completing the baseline survey, approximately 50% of respondents were willing to test a wearable watch in conjunction with florio HAEMO to support management and monitor daily activities. The follow-up survey will report adherence and satisfaction data and include additional data

FIGURE 4 Difficulties experienced using florio HAEMO (N = 66). Note that respondents could provide more than one answer to the multiple-choice questions
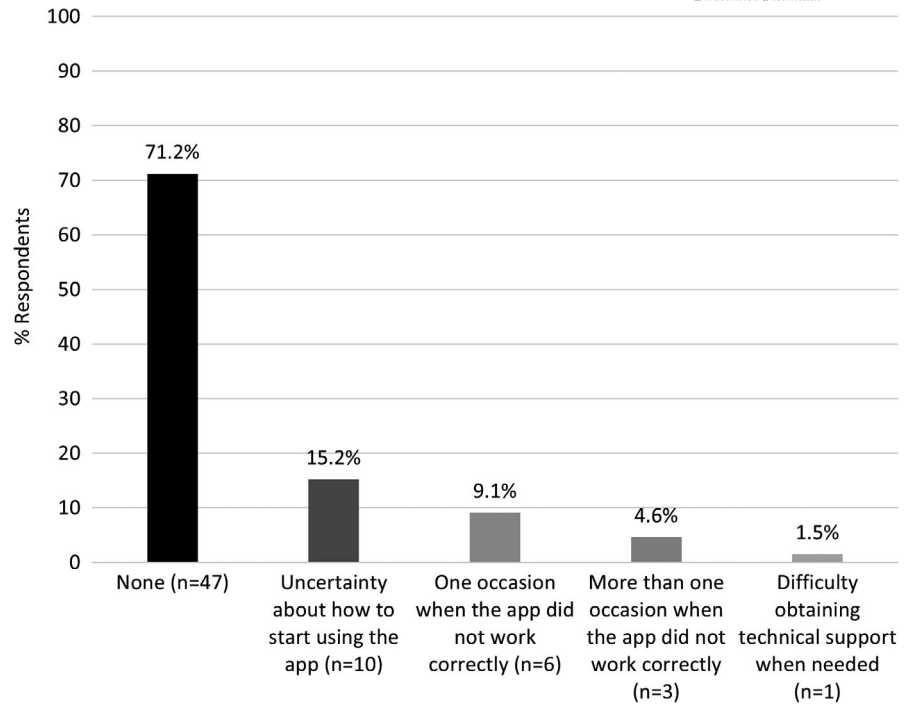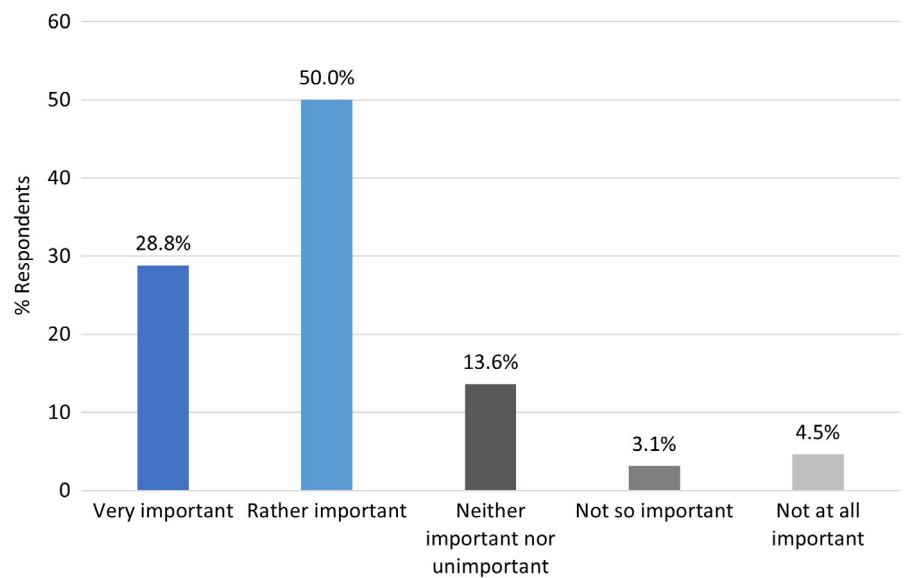
FIGURE 5 Importance of florio HAEMO in bringing more certainty to life for people living with hemophilia and/or their caregivers (N = 66)

on people with hemophilia using florio HAEMO obtaining data from a wearable. The use of a wearable device may assist in tracking physical activity more precisely. Still, it should also be emphasized that the patients are always informed about their current clotting factor activity estimates.

Although our study provides valuable insight into florio HAEMO's acceptability, the small survey size may affect the sample's representativeness. The patients represented in the survey were primarily children, adolescents, or young adults aged <50 years, limiting how applicable the results are to older (aged >50 years) people with hemophilia. The participation rate of those invited to complete the survey was not optimal, so results could be affected by bias; those participating might have higher satisfaction as they were willing to participate, compared with those who did not participate. We did not have characteristics of

nonparticipants, which might have allowed better understanding of the direction of such bias. The survey questionnaire design did not include any standardized validity assessment, and no formal statistical comparison was performed, so results should be interpreted with caution. We acknowledge that self-reported surveys are subject to measurement errors; the median duration using the florio HAEMO app was 3–4 weeks in our survey, which is a relatively short period. However, this timeframe was selected following psychometric assessment advice and based on the optimum recall period (i.e., the optimum memory time for patients to recall app preference following switching).[22] The subgroup analysis indicates that patient satisfaction, preference, and clinical benefits using florio HAEMO may increase with longer use; however, these initial trends should be interpreted with caution and require further investigation because of the low number of respondents in

the survey. Notably, florio HAEMO underwent significant software upgrades in the initial launch phase to rectify early software issues. In addition, we cannot comment on whether there are any differences in responses between those who had previously used another hemophilia monitoring app and those who used the florio HAEMO app for the first time.

5 | CONCLUSIONS

Our results suggest that the florio HAEMO hemophilia monitoring application is easy to use, intuitive, and preferred by people with hemophilia and their parents/caregivers, resulting in more certainty in daily activities. florio HAEMO may be used by individuals with hemophilia of all ages receiving prophylaxis with any factor concentrate or caregivers. In addition, the software further empowers patients with personal health insights, which helps to facilitate patient-HCP communication and offers the potential for improved monitoring and therapeutic outcomes in hemophilia.

AUTHOR CONTRIBUTIONS
All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in revising the article critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

ETHICAL APPROVAL
This cross-sectional survey was approved by University Hospital Bratislava Ethics Committee.

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SUPPORTING INFORMATION

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