ORIGINAL PAPER

Male infertility, what Mobile Health Applications "know": quality analysis and adherence to European Association of Urology Guidelines

Giovanni Maria Fusco [1], Luigi Cirillo [1], Marco Abate [1], Simone Morra [1], Vincenzo Morgera [1], Biagio Barone [1], Felice Crocetto [1], Gianluigi Cacace [1], Francesco Di Bello [1], Lorenzo Spirito [2], Celeste Manfredi [2], Davide Arcaniolo [2], Alessandro Palmieri [1], Ciro Imbimbo [1], Vincenzo Mirone [1], Luigi Napolitano [1]

[1] Department of Neurosciences, Reproductive Sciences and Odontostomatology, Urology Unit, University of Naples "Federico II", Naples, Italy;
[2] Urology Unit, Department of Woman, Child and General and Specialized Surgery, University of Campania "Luigi Vanvitelli", Naples, Italy.

Summary
Introduction: Male infertility (MI) is one of the most important worrying topics for the fertile age population. Nowadays, several mobile health applications (MHAs) have been developed to help and assist patients suffering from male infertility (MI), but their quality and adherence to the guidelines is not solved issue yet.
Materials and methods: On 2nd July 2022, an observational cross-sectional descriptive study of all MHAs on male infertility was conducted: a search on both the iTunes App Store and Google Play Store was performed. Our group reviewed all MHAs, evaluating the quality, using Mobile Application Rating Scale (MARS), and the adherence to European Association of Urology guidelines, with a special tool created for this manuscript.
Results: In the final analysis we included 10 MHAs: 20% (n = 2) from the iTunes App Store and 80% (n = 8) from the Google Play Store. Across the sample, 80% (n = 8) of the apps provided general information on MI, 60% (n = 6) focused on diagnosis and 50% (n = 5) focused on treatment options, respectively. According to MARS tool, the mean score was 2.18 (0.78), 3.78 (0.36), 3.0 (0.53), 3.19 (0.45), 2.18 (0.54) for Engagement, Functionality, Aesthetic, Information and Subjective quality, respectively. According to EAU Adherence Score, the highest score was reported by "Infertilità" with 12/15 points while the lowest score was reported by "Fertility Diet Guide", 0/15 points.
Conclusions: Nowadays, MHAs present in the market are not a reliable source of information on MI. An ideal MHAs should be based on scientific evidence, user friendly, respecting privacy and security laws, making patients feel capable and confident to change personal behavior or attitudes.

KEY WORDS: *Keywords: App; Male infertility; E-health; Mobile phone; MARS.*

INTRODUCTION

In recent years new technologies, such as Internet, social media telemedicine, and *mobile health* (mHealth) have rapidly grown, particularly during SARS COV 2 pandemic outbreak (1-7), supporting patients in several medical and surgical fields and increasing medication adherence and self-management of diseases. The World Health Organization has defined mHealth as "*a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices*" (8). Nowadays, the global usage of smartphones stands at 3.5 billion (9). An increasing number of mobile health applications (MHAs) are available for download through the *iTunes App Store* and *Google Play Store* (10).

Male infertility (MI) is defined as the inability of a male to make a fertile female pregnant, also for a minimum of at least one year of unprotected intercourse. Male factor contributes about 50% of all cases of infertility (11, 12). Contemporary data suggests that there has been a decline in global fertility rates from 4.7 to 2.4 live births between 1950 and 2017 (13, 14). Several reasons were recognized as causes of impaired sperm parameters, among the main ones, varicoceles (15), hypogonadism (16), and genetic disorders (17). Treatment can be divided in medical and surgical treatment (Lifestyle modifications (18), antioxidant therapy (19, 20), hormone stimulation therapy (21, 22) TESE and other surgical approaches (23).

MHAs development has not regulated, and several apps, currently available (10) in several fields, including andrological, are characterized by poor-quality. The most important evaluation criteria are the number of downloads and the user ratings (24). Due to this searching for high-quality information is still more difficult. Mobile Application Rating Scale (MARS), represents the most widely used and recommended tool providing quantitative, and validated evaluation of MHAs (25, 26). Several studies reported data about MHAs evaluation and adherence to guidelines in different medical and surgical setting (27-30).

To the best of our knowledge, no previous studies analyzed the quality of MHAs for MI and their adherence to guidelines. Our current project aims to provide an overview of MHAs, available on the market, developed for MI analyzing quality through the MARS and their adherence to *European Association of Urology* (EAU) guidelines.

MATERIALS AND METHODS

Search strategy

On 2nd July 2022, an observational cross-sectional descriptive study of all MHAs on MI was conducted. A search on both the iTunes App Store and Google Play Store was performed using an IPhone 13 and a Samsung s10, respectively. "*Male infertility*" AND/OR "*diagnosis*", AND/OR "*treatment*" were the keywords used for search tab. These keywords were used according to the search strategy of Google Play Store and iTunes App Store, which is based on finding keywords in titles, app descriptions and tags. We excluded information available in books, and in other formats.

Two authors (GC, VM) screened separately in iTunes App Store and Google Play Store apps during the search by reading the title and description in the app store. One reviewer conducted a search in the iTunes App Store, and the other in the Google Play Store.

Reviewers created an Excel form to report all MHAs and in the second time they were screened according to the exclusion criteria. They included in the present studies all MHAs regarding MI, providing a service to patients, in English, and free to download. MHAs not specifically focused on MI, not allowing access to all users and those not available in English were excluded.

On 4th July 2022 reviewers downloaded and installed the apps on their personal mobile devices. They interacted for thirty minutes with each app to explore its features before completing the MARS and then they evaluated adherence to EAU guidelines. In case of MHAs present in both stores, only the iTunes App Store version was analyzed. A total of 35 apps were found by our search, 30 (85.7%) of them were from the Google Play Store (Android) and 5 (14.3%) of them were from the iTunes App Store. Of all the MHAs, 17 were excluded: present in both stores (n=1), not in English (n = 3) and off-topic (n = 13). Only 18 MHAs were eligible for the final evaluation and were downloaded. Finally, 10 MHAs were included in the final review after removing 8 MHAs that met exclusion criteria after download. The search strategy was performed according to PRISMA statement (Figure 1). MHAs characteristics were reported in the Table 1.

Assessment of app quality

Mobile Application Rating Scale (MARS) was used to assess the quality of MHAs. MARS is a multidimensional instrument of 23 structured questions evaluating different domains: engagement, functionality, esthetics, information, app subjective quality, and app-specific, showing a very acceptable reliability and validity. Engagement (interest, customizability, interactivity), Functionality (performance, ease of use, navigation), Aesthetics (layout, graphics, visual appeal) and Information (accuracy of app, credibility, evidence base). Subjective (recommendable, worth buying) and 1 category of subjective quality. Each category score is the mean of the different items, rated on a 5-point Likert-type scale (from 1 = inadequate to 5 = excellent) within its category. The mean of the 4 app quality category scores is used to calculate overall quality score and the final score range from 0 to 5. A score of between 1 and 2/5 is considered as 'poor' quality, while 3/5 is 'acceptable' and at least 4/5 is 'good' quality. If scores differed by a single point, reviewers use the mean of the two ratings, while if scores differed by more than a single point, reviewers solve the discrepancy through discussion and consensus agreement. Mean scores were calculated for each domain and an overall quality score was calculated based on the aggregated mean values for each of the four domains. The mean score for subjective quality is calculated.
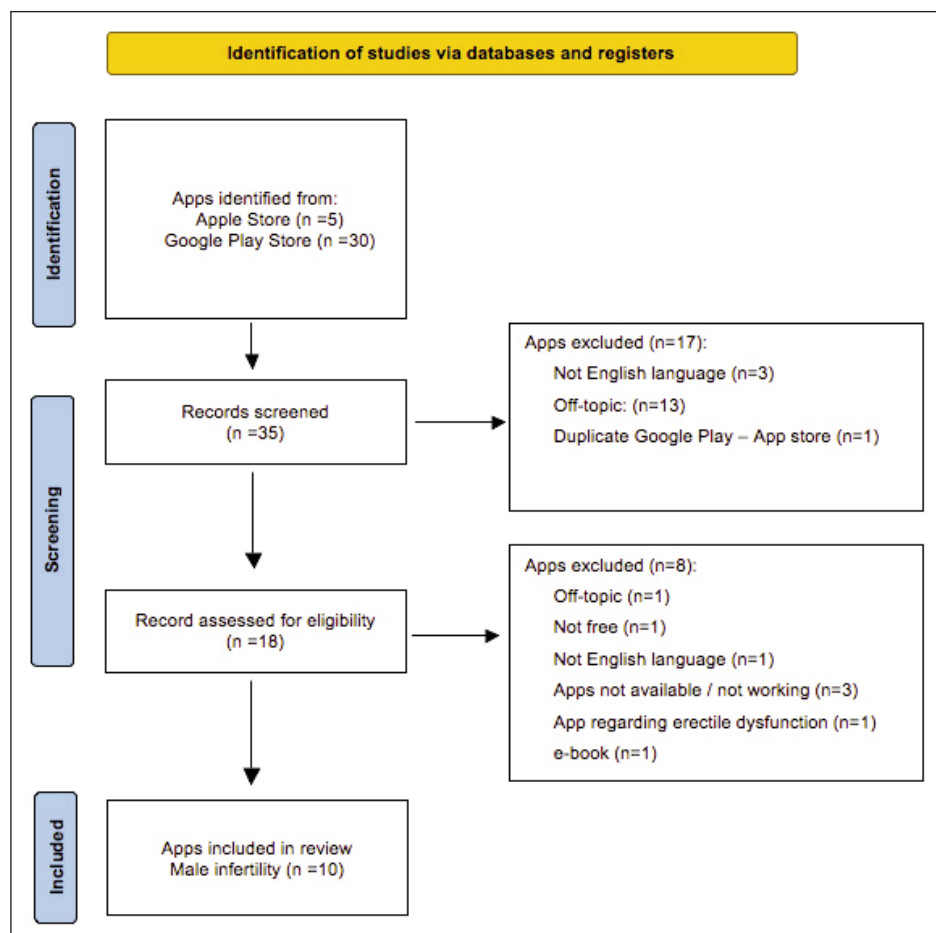
Figure 1.

Table 1.
General characteristics of applications.

Name of application	Android/Apple/Both	Download	Producer	Category	Focus
Infertility solutions	Android	500	Dagana Apps	Instruction	Definition, Causes, Diagnosis, Treatment
Fertility treatment	Android	10000	Di natale	Health & fitness	Definition, Diagnosis, Treatment
Sperm count advice	Android	10000	moreFlow	Health & fitness	Diet , Workouts, Lifestyle
Infertility and its management	Android	100	FUMO	Medicine	Definition, Causes and Risk factors, Diagnosis
Fertility diet guide	Android	10000	Prestige Worldwide Apps, Inc	Health & fitness	Diet, Lifestyle (male/female)
Infertility	Android	1000	Nature Healthy Care	Entertainment	Definition, Causes, Risk factors, Diagnosis, Treatment
How to get pregnant fast	Android	10000	Saleha Group	Entertainment	Causes, Diagnosis, Treatment
How to get pregnant fast	Android	5000	Dvapps-bsl	Social	Causes, Diagnosis
YO Sperm Test Wi-Fi	Apple	n.a.	Medical Electronic System, LLC	Medicine	Informative, Practital (marketing)
VaricoHealth	Apple	n.a.	Varicocele Healing Ltd.	Health & fitness	Risk factors, Causes, Lifestyle

Assessment of app adherence to EAU guidelines
Based on the EAU guidelines 2022 on Sexual and Reproductive Health, an adherence checklist of five items (definition, physiopathology, diagnosis, risk factors and treatment) according to the sections (9). Two independent reviewers (VM, and CF, urologists with high experience in MI) analyzed separately apps for their adherence to EAU guidelines. According to criteria used in similar studies, raters gave each app a score from 0 to 3 for each of the five items. A score of "0" indicated no adherence to guidelines. A score of "1" indicated a weak adherence. A score of "2" indicated a partial or moderate adherence. A score of "3" indicated strong adherence. Where coding scores differed by 1 point, the average of the two ratings was taken. If there was a greater than 1-point discrepancy, a third author reviewed apps and resolved the discrepancy.
The possible score on the checklist ranged from 0 to 15 for each app. To facilitate evaluation, adherence to the checklist was arbitrarily considered low with a total score ranging from 0 to 5, medium (6-10), and high (11-15).

Statistical analysis
Means, standard deviations and range values for each MARS domain, as well as the overall quality scores and subjective quality scores, were calculated. Means and standard deviations were reported for continuous variables while frequencies and percentages were reported for categorical variables. Pearson's correlations were used to analyze correlations between app downloads and MARS ratings. Microsoft excel was used for data segregation and analysis. Statistical analysis was conducted using IBM SPSS software (*version 25, IBM Corp, Armonk, NY, USA*), considering p < 0.05 as statistically significant.

RESULTS
In the final analysis we included 10 MHAs: 20% (n = 2) from the iTunes App Store and 80% (n = 8) from the

Google Play Store. Across the sample, 80% (n = 8) of the apps provided general information on MI, 60% (n = 6) focused on diagnosis and 50% (n = 5) focused on treatment options, respectively. Risks factors were reported in 50% (n = 5) MHAs. Information of downloads were available for 80% (n = 8) MHAs out of the 10 reviewed. Downloads were not reported in MHAs downloaded by iTunes Apple Store. All the apps were planned to be used by patients. No information about MHAs rating was available. MARS scores are represented in Table 2.

Engagement
The score in this section was based on a 5-point *Likert* scale in 5 subscales (*Entertainment, Interest, Customization, Interactivity and Target-group*). The mean score was 2.18 (0.78). The "*YO Sperm Test Wi-Fi*" app produced by "*Medical Electronic System, LLC*" received the highest score for the engagement.

Functionality
The score of the Functionality section was based on a 5-point Likert scale in 4 subscales (*Performance, Ease of use, Navigation and Gestural design*). The mean score was 3.78 (0.36).

Aesthetics
The aesthetics section was formed by a 5-point Likert scale in 3 subscales (*Layout, Graphics, Visual Appeal) and the mean score was 3.0 (0.53). "Fertility Diet Guide*" pro-

Table 2.
MARS evaluation.

Apps Name	Engagement (section A)	Functionality (section B)	Aesthetic (section C)	Information (section D)	Overall mean score (SD)	App subjective quality (section E)
YO Sperm Test Wi-Fi	4.2	4	3.67	4.17	4.01 (0.24)	3.5
VaricoHealth	1.8	3.25	2	2.8	2.46 (0.68)	2.5
Infertility solutions	2.6	4	2.7	3.7	3.25 (0.70)	2
Fertility treatment	2.2	4	3.3	3.25	3.18 (0.74)	1.75
Sperm count advice	1.6	4	3.3	3.25	3.04 (1.01)	2.5
Infertility and its management	1.6	3.25	2.7	3.25	2.7 (0.78)	1.75
Fertility diet guide	2.2	4	3.7	3	3.23 (0.80)	2
Infertility	1.6	3.25	2.7	3	2.64 (0.73)	1,75
How to get pregnant fast	2	4	2.7	2.75	2.86 (0.83)	2
How to get pregnant fast	2	4	3.3	2.75	3.01 (0.84)	2
Mean (SD)	2.18 (0.78)	3.78 (0.36)	3.0 (0.53)	3.19 (0.45)	3.04 (0.43)	2.18 (0.54)

SD = standard deviation.

Table 3.
EAU guidelines adherence.

Name	Definition	Physiopathology	Risk factors	Diagnosis	Treatment
YO Sperm Test Wi-Fi	1	1	2	3	2
VaricoHealth	0	1	1	0	0
Infertility solutions	2	0	2	1	2
Fertility treatment	1	0	0	1	2
Sperm count advice	0	0	0	0	1
Infertility and its management	0	2	3	2	1
Fertility diet guide	0	0	0	0	0
Infertility	2	3	3	2	2
How to get pregnant fast	0	0	1	2	1
How to get pregnant fast	0	0	2	1	0
Mean (SD)	0.6 (0.84)	0.7 (1.05)	1.4 (1.17)	1.2 (1.03)	1.1 (0.87)

SD = standard deviation.

duced by "*Prestige Worldwide Apps, Inc*" reached the highest aesthetics score.

Information
The information section was formed by a 5-point *Likert* scale in 7 subscales. The mean score was 3.19 (0.45). The "*YO Sperm Test Wi-Fi*" app produced by "*Medical Electronic System, LLC*" received the highest score of Information.

Overall mean score
The App quality mean score correspond to the mean of the sum of Engagement, Functionality, Aesthetic and Information scores. The mean score was 3.04 (0.43). The "*YO Sperm Test Wi-Fi*" app produced by "*Medical Electronic System, LLC*" received the highest mean score of 4.01 (0.24), while "*VaricoHealth*" produced by "*Varicocele Healing Ltd*", received the lowest mean score of 2.46 (0.68).

Subjective quality
The subjective quality section consisted of 4 items. The score was 2.18 (0.54). The "*YO Sperm Test Wi-Fi*" app produced by "*Medical Electronic System, LLC*" received the highest score of Subjective quality section of 3.5.

EAU adherence checklist
EAU guidelines adherence was evaluated and the EAU adherence scores were reported in Table 3. The mean Definition score was 0.6 (0.84), with 60% (n = 6) apps reporting a score of zero; the mean Physiopathology score was 0.7 (1.05) with 60% (n = 6) apps reporting a score of zero; the mean risk factors' scores was 1.4 (1.17) with 30% (n = 3) apps reporting a score of zero; the mean diagnosis score was 1.2 (1.03) with 30% (n = 3) apps reporting a score of zero; the mean treatment score was 1.1 (0.87) with 30% (n = 3) apps reporting a score of zero. The highest score was reported by "*Infertilità*" produced by "*Nature Healthy Care*" with an overall EAU Adherence score of 12 points. The lowest score was reported by "*Fertility Diet Guide*", produced by "*Prestige Worldwide Apps, Inc*" with an overall EAU Adherence score of zero points.

Variable correlations
A Pearson correlation coefficient was computed to assess the linear relationship between variables and number of downloads. The only statistically significant correlation was found between the number of download and the section on "*risk factors*" of the adherence to the EAU guidelines scoring system, with r = -0.928, p = 0,001.

DISCUSSION
The aim of the present study was to give an overview of MHAs for MI, currently available on the market in order to assess their quality and adherence to EAU guidelines. To the best of our knowledge, no previous studies examined this topic, so we addressed this void and identified several noteworthy observations.
First, of all 10 apps on MI eligible for the analyses, the majority were present on Google Play Store and 80% reported general information on MI. However, only half of the apps reported information on diagnosis and treatment options. Therefore, the developer of apps should improve the quality of the content present in the apps in order to allow a greater understanding of the phenomenon of MI.
Second, according to MARS score criteria, the lowest mean score was reported for the "*Engagement*" section, while the highest mean score was reported for the "*Functionality*" section. These findings are in agreement with *O'Connor et al.* (28) and indicate that the apps were generally better designed in terms of their usability but may have lacked behavioral and design features associated with sustained usage.
Third, according to EAU Guidelines Adherence scoring system, the lowest mean score was reported in the "*Definition*" section, while the highest score was reported in the "*Risk Factors*" section. The overall scores of this tool are very low. These results are corroborated by other published studies highlighting a dramatically low adherence to guidelines. This is due to lack of involvement of healthcare MHAs development, representing a great limit, that should be addressed in their future development. On the other side collaboration with healthcare does not meaning high quality. In fact, as reported by *Dantas et al.* in MHAs for rheumatic disease, not developed for commercial purposes, but created with a partnership between industry/developers and academic institutions, the quality was still low (29).
Fourth, according to MARS, the best MHA currently present on the market is represented by "*YO Sperm Test Wi-Fi*" developed by "*Medical Electronic System, LLC*" . This app reported the highest score in every single section of this quality tool. It's noteworthy that this app reported the highest score in the "*Engagement*" section (4.2), followed by Information (4.17), and Functionality (4). To the best of our knowledge no previous studies reported this finding in Engagement, which generally is the lowest reported score, because MHAs are better designed for their usability (efficient and easy to use) and lacked behavioral and design features. This is corroborated by the Functionality score which is the highest reported score.
YO Sperm Test Wi-Fi can make patients feel that they are participating in the management of their disease. The

most reported findings suggest developing MHAs with these characteristics.

Taken together, MHAs have a great potential to control the spread of misinformation, raise awareness, helping and informing patients (9). Given the rising role of new technologies in the various health-care services, a formal standardization of contents addressed to nonmedical users would be desirable. The majority MHAs currently present in the market are not good enough to be used as reliable source of information on MI. However, *Kruglova et al.* developed a MHA, Infotility XY, to promote men's reproductive health (31). Their study showed evidence of the feasibility of MHAs to improve men's knowledge about fertility, about risks factor. In fact, men involved in the study, identified more risk factors after using the app (M = 17.14, SD = 4.32) compared to before (M = 11.12, SD = 4.53). Despite this, nowadays there were a multitude of MHAs lacking in quality and correct information. This study has several strengths: this is the first study evaluating the content, the quality, and the adherence to EAU guidelines about MI; we performed a rigorous search, screening, and analysis on iTunes and Google Play Store; reviewer had experience in MARS using. Our research is not avoided by some limitation: reproducibility of the research turns out to be complex due to the working method of the App Store and Google Play Store (the visibility of apps depends on the device and on the country where the search is performed); the exclusion criteria, which led to the exclusion of paid apps; the guidelines developed for healthcare and not for patients and the constant production of new MHAs.

Conclusions

Nowadays, MHAs present in the market are not a reliable source of information on MI. An improvement by the app developers would be welcome, in order to make the apps good both in terms of content and in terms of compliance with the guidelines. Therefore, an ideal MHAs should be based on scientific evidence, user friendly, respecting privacy and security laws, making patients feel capable and confident to change personal behavior or attitudes. Interesting, it could be the involvement of patients in the development, design, and validation of MHAs.

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Correspondence

Giovanni Maria Fusco, MD
giom.fusco@gmail.com

Luigi Cirillo, MD
cirilloluigi22@gmail.com

Marco Abate, MD
marcoabate5@gmail.com

Simone Morra, MD (Corresponding Author)
simonemorra93@gmail.com

Vincenzo Morgera, MD
vincemorgera87@gmail.com

Biagio Barone, MD
biagio.barone@unina.it

Felice Crocetto, MD
felice.crocetto@unina.it

Gianluigi Cacace, MD
cacace.gianlu@gmail.com

Francesco Di Bello, MD
fran.dibello12@gmail.com

Alessandro Palmieri, MD
info@alessandropalmieri.it

Vincenzo Mirone, MD
mirone@unina.it

Ciro Imbimbo, MD
ciro.imbimbo@unina.it

Luigi Napolitano, MD
luiginap89@gmail.com

Department of Neurosciences, Reproductive Sciences and Odontostomatology,
Urology Unit, University of Naples "Federico II", Naples, Italy
Via Sergio Pansini n 5, Naples (NA), Campania (Italy)

Lorenzo Spirito, MD
lorenzospirito@msn.com

Celeste Manfredi, MD
manfredi.celeste@gmail.com

Davide Arcaniolo, MD
davide.arcaniolo@unicampania.it

Urology Unit, Department of Woman, Child and General and Specialized Surgery,
University of Campania "Luigi Vanvitelli", Naples, Italy