

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Web-based internet searches for digital health products in the United Kingdom before and during the COVID-19 pandemic: a time-series analysis using app libraries from the Organisation for the Review of Care and Health Applications (ORCHA)
<b>AUTHORS</b>	Leigh, Simon; Daly, Rob; Stevens, Sebastian; Lapajne, Luka; Clayton, Charlotte; Andrews, Tim; Ashall-Payne, Liz

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Kamulegeya, Louis The Medical Concierge Group
<b>REVIEW RETURNED</b>	02-Jul-2021

<b>GENERAL COMMENTS</b>	<ol style="list-style-type: none"><li>1. Need to harmonize the research question (study aim) stated in the last paragraph under the introduction to the one stated under the methodology section.</li><li>2. The implemented research design does not complete the entire story/narrative that would conclusively state increased appetite/drive for DHPs. True this was stated as a limitation but this downplays the methodology.</li><li>3. It is not clear on what informed the choice of the disease conditions chosen that informed on the categorizations of the search results? Was it based on consensus of the research team? Was it based on common disease diagnoses or?</li><li>4. It is not clear on what data variables were analysed in Excel and what proceeded to be analysed in Stata?</li><li>5. The authors should re-read the paper and double all spelling and grammatic and punctuation errors.</li></ol>
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<b>REVIEWER</b>	Broenneke, Jan German Federal Ministry of Health, health innovation hub
<b>REVIEW RETURNED</b>	04-Sep-2021

<b>GENERAL COMMENTS</b>	<p>The paper addresses the question of patients' interest in DHP and with that contributes to the important current debate about the value of DHP. The questions of patients' interest in, demand for, as well as actual usage of DHP is vital in this debate as DHP are especially dependent on patients' compliance and - at the same time - are specifically useful in measuring the compliance.</p> <p>The paper in general is very interesting, well balanced and methodically sufficient. Limitations are described openly. The paper in general is a nice and fluent read. The main point of</p>
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critique is the lack of two definitions in the research question that, consequently, lead to unclear implications:

1) DHP are not defined well enough. Are DHP only (regulated) medical devices with a medical purpose corresponding to Art. 2 Medical Device Regulation (or the corresponding future British regulation), or does it include simple "lifestyle apps" with no medical purpose, as the category "Fitness, diet & weight loss" implies? If lifestyle apps are included, the clinical background given in the introduction and especially the conclusions drawn for clinical practice (page 17) are less clear than stated in the paper. As clinicians will most likely recommend DHP with a minimum of safety and clinical evidence, the increasing interest of patients in lifestyle apps is probably not of (much) interest to them.

2) The title's "App-etite" is not defined well enough: Throughout the paper, the most used word is "demand", on page 14 used in combination with "interest". There is a difference for a demand for DHP and an interest in DHP. The chosen method is suitable to assess an interest in rather than a real demand. The assessment of interest in DHP is a valuable contribution but should not be confused with the assessment of a (stronger) demand for DHP. The definition of "app-etite" is also important in connection with the aforementioned definition of DHP: A demand for certified medical devices is something different than an interest in lifestyle apps, which again differs from an interest in medical devices or a demand for lifestyle apps.

If possible, I would limit the research on medical devices and stick with the term "interest". If lifestyle apps should be/stay included, a corresponding statement should be made with regard to the relevance for clinical practice. If the term "demand" should be used, the validity of the endpoint "number of searches" should be demonstrated, for example by proving a certain conversion rate, indicating more than an interest

## VERSION 1 – AUTHOR RESPONSE

### REVIEWER 1

9. **Reviewer 1 comment 1:** Need to harmonize the research question (study aim) stated in the last paragraph under the introduction to the one stated under the methodology section.

**Author response:** Thank you, we have ensured that these statements mirror one another in meaning, while also making the changes requested by the editor. In doing so we have scaled back the research aim to the following, which is a little less far reaching, and within the confines of what the study can feasibly tell us.

#### **INTRODUCTION:**

*"The aim of this study is to determine how internet searches for DHPs for various health conditions has changed since COVID-19 lockdown measures were introduced in March 2020 and*

*throughout the pandemic. Furthermore, this study will also explore whether changes in search volumes for DHPs differed by therapeutic area.”*

**METHODS:**

*“The methodology for this study is a retrospective time-series analysis of real-world internet searches for DHPs within ORCHA’s Digital health library, split over two time periods; before and after the initiation of COVID-19 lockdown procedures in the UK, which commenced on March 23<sup>rd</sup> 2020. Our aim was to determine if searches for DHPs changed following the first phase of lockdown, and throughout the pandemic. Additionally, the study aims to explore whether changes in search volumes for DHPs differed by therapeutic area.”*

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10. **Reviewer 1, comment 2:** The implemented research design does not complete the entire story/narrative that would conclusively state increased appetite/drive for DHPs. True this was stated as a limitation but this downplays the methodology.

**Author response:** We agree completely and have received similar comments from the editor. We have since removed all mentions of the largely undefined outcome of ‘app-etite’ and instead focused on objective changes in internet search volumes. These amendments have been made throughout the manuscript. We have also added significantly to the limitations section in highlighting that increased search volumes are not a guarantee for a shift in perspective. Covid-19 may have simply accelerated pre-existing beliefs among those searching for DHPs, out of necessity (due to a lack of F2F care), rather than out of genuine interest in these technologies.

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11. **Reviewer 1, comment 3:** It is not clear on what informed the choice of the disease conditions chosen that informed on the categorizations of the search results? Was it based on consensus of the research team? Was it based on common disease diagnoses or?

**Author response:** We agree. Thank you for pointing this out. We have since made this process more clear as you recommend.

*“These condition areas were identified following multi-disciplinary input from three healthcare professionals (a midwife, a pharmacy specialist lead, and an ophthalmologist) and a health economist, with the aim of covering a broad representation of functions and conditions throughout the human body. An iterative process was utilized where each contributor added to (or recommended removing conditions) from the contribution of the last. Once all contributors had the opportunity to recommend therapeutic areas for inclusion, a final discussion between all four contributors took place, at which point the condition areas were finalized.”*

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12. **Reviewer 1, comment 4:** It is not clear on what data variables were analysed in Excel and what proceeded to be analysed in Stata?

**Author response:** Apologies, this should have been much clearer. In the process of minimising word count we have lost some meaning and interpretation. This has now been clarified as demonstrated below.

*“Data cleaning was performed using Microsoft Office Excel 2013 (Microsoft ®, Redmond, Washington, USA), with all statistical analyses conducted using Stata 14.”*

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**13. Reviewer 1, comment 5:** The authors should re-read the paper and double all spelling and grammatic and punctuation errors.

Author response: Thank you. We have done as suggested.

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## **REVIEWER 2**

**14. Reviewer 2, comment 1:** The paper addresses the question of patients' interest in DHP and with that contributes to the important current debate about the value of DHP. The questions of patients' interest in, demand for, as well as actual usage of DHP is vital in this debate as DHP are especially dependent on patients' compliance and - at the same time - are specifically useful in measuring the compliance.

**Author response:** Thank you. We have not made any changes based on this comment.

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**15. Reviewer 2, comment 2:** The paper in general is very interesting, well balanced and methodically sufficient. Limitations are described openly. The paper in general is a nice and fluent read. The main point of critique is the lack of two definitions in the research question that, consequently, lead to unclear implications: 1) DHP are not defined well enough. Are DHP only (regulated) medical devices with a medical purpose corresponding to Art. 2 Medical Device Regulation (or the corresponding future British regulation), or does it include simple "lifestyle apps" with no medical purpose, as the category "Fitness, diet & weight loss" implies? If lifestyle apps are included, the clinical background given in the introduction and especially the conclusions drawn for clinical practice (page 17) are less clear than stated in the paper. As clinicians will most likely recommend DHP with a minimum of safety and clinical evidence, the increasing interest of patients in lifestyle apps is probably not of (much) interest to them.

**Author response:** Thank you for suggestion. We agree entirely. Although we did stratify the apps under consideration into condition areas, including a "fitness, diet and weight loss" category, the DHPs under consideration should have been characterised earlier in the manuscript. For the

purpose of this analysis the DHPs subject to internet searches include all types of DHP, from simple exercise suggestions and dietary advice to regulated medical devices, including those which promote diet and fitness (labelled in the corresponding category), to those suggesting insulin doses, and those which aim to distinguish a melanoma from a clinically benign skin mole.

**This can be seen here in the methods section:**

*“The methodology for this study is a retrospective time-series analysis of real-world internet searches for DHPs within ORCHA’s Digital health library, split over two time periods; before and after the initiation of COVID-19 lockdown procedures in the UK, which commenced on March 23<sup>rd</sup> 2020. For the purpose of this analysis, DHPs were defined as health-apps, including all health-apps with the potential to improve health outcomes, not limited to medical devices, but also including diet and fitness health-apps.”*

We have also expanded our coverage of this in the discussion, and suggested that further research is required to unpick where any increases in search volumes were experienced. For example, were these predominantly in diet and fitness DHPs, or among those which are notifiable medical devices?

**An example from the future research section of the discussion is provided below:**

*“These restrictions undoubtedly impacted access to incumbent services and therefore the argument may be made that DHPs were sought as an interim or ‘placeholder’ measure in order to fulfil unmet clinical needs. While this is a plausible hypothesis, it does require confirming, while the future role of DHPs beyond the pandemic, as things slowly begin to normalize, also requires exploration. Attention should be paid to the specifics of DHPs and how willingness to use such technologies differs by functionality. It is plausible that members of the public were happy to use DHPs which had limited functionality in the absence of being able to visit a qualified HCP, but would have concerns about using DHPs classed as medical devices. Unfortunately this could not be discerned in this analysis and should be addressed, in addition to the other points raised above, before we can determine whether the observed increase in searches for DHPs was a one-time occurrence, or indeed, the start of a new era of digital medicine.”*

With regard to your comment r.e. clinicians only recommending apps with clinical evidence, while this makes sense for health-apps with high degrees of functionality (and therefore a higher inherent risk, if DHPs were to be unproven and unevaluated), however this is not necessarily the case for all DHPs. For example, within the UK, the NHS has been advised to follow guidance from the National Institute for Health and Care Excellence (NICE), and more specifically, the NICE Evidence Standards Framework (ESF). This framework for the evaluation of evidence for DHPs sets out a graded system for evidence, whereby clinicians are advised against requiring empirical evidence of effectiveness where the inherent risk of failure (no tangible impact on health outcomes), is low. Such DHPs include what NICE refers to as tier 1 and tier 2 DHPs. These include DHPs aimed at improving fitness, providing general lifestyle advice, etc. For such DHPs, simple proof that the concepts and recommendations provided are (1) widely accepted, (2) up to date, and (3) from credible referenced sources are usually sufficient.

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16. **Reviewer 2, comment 3:** The title's "App-etite" is not defined well enough: Throughout the paper, the most used word is "demand", on page 14 used in combination with "interest". There is a difference for a demand for DHP and an interest in DHP. The chosen method is suitable to

assess an interest in rather than a real demand. The assessment of interest in DHP is a valuable contribution but should not be confused with the assessment of a (stronger) demand for DHP. The definition of "app-etite" is also important in connection with the aforementioned definition of DHP: A demand for certified medical devices is something different than an interest in lifestyle apps, which again differs from an interest in medical devices or a demand for lifestyle apps.

**Author response:** Thank you. This is advice that was mirrored in the suggestions of the editor. We have since been through the manuscript and ensured that the term 'appetite' has been removed, and replaced with interest, or the longer explanation of 'internet searches for DHPs'.

We agree entirely that there is a clear distinction between interest and demand, and the manuscript is now solely presented with 'interest' in mind. We believe we have addressed your concern regarding different types of apps in the response to the previous comment.

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17. **Reviewer 2, comment 4:** If possible, I would limit the research on medical devices and stick with the term "interest". If lifestyle apps should be/stay included, a corresponding statement should be made with regard to the relevance for clinical practice. If the term "demand" should be used, the validity of the endpoint "number of searches" should be demonstrated, for example by proving a certain conversion rate, indicating more than an interest.

**Author response:** At present, a separation of the data utilised for the analysis in terms of app functionality is not possible. We can separate for diet and fitness DHPs versus all other types of DHP, as already performed in the findings, however going one level further and classifying as lifestyle or otherwise for all DHPs is a complicated matter. This is because many apps contain lifestyle components to some extent. Additionally, to complicate things further, some exercise apps are now classed as medical devices, particularly if they are aimed at a specific high risk population (including those with cardiovascular conditions), and they aim to 'prescribe' highly individualised exercise recommendations to users. This is an area of digital health research which we believe requires far more depth and discussion than what could possible be provided within the confines of this analysis (alongside what is already presented here). We have amended the future research section of the analysis as demonstrated below:

**Future research:**

*“A large part of this process is informing, and enabling healthcare professionals to also recognise this opportunity, to become more actively involved in the provision of high-quality, trusted and safe DHPs for a variety of conditions. This is not limited solely to high functioning medical devices, but also to DHPs with the aim of improving lifestyle decisions and promoting healthy living, with interest in DHPs from both ends of the spectrum increasingly significantly, as observed in this analysis.”*

As suggested we have also removed all mentions of demand and substituted this with interest or "internet searches".