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6	Study Protocol	for a Two-Phase Randomized Evaluation of Large Language
7	Models in Adhe	erence to Evidence-Based Health Communication Guidelines
8	for Breast and P	rostate Cancer Screening: The Role of User Prompt Specificity
9		and Minimal Interventions (BOOST-AI)
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33 Introduction

34 In Western healthcare systems, there is a growing emphasis on ensuring that health information is 35 communicated in a way that allows individuals to make well-informed decisions about their medical 36 treatments. Central to this is the clear presentation of patient-relevant benefits and risks of medical 37 procedures.¹ To achieve this, evidence-based guidelines, such as the Guideline for the Development of 38 Evidence-based Patient Information² and the Working Group for Good Practice in Health Information 39 (GPHI)³, provide a structured framework for health communication. These guidelines stress the importance of using precise numerical data to present risks and benefits, contextualizing information 40 41 within a relevant reference class, and offering balanced explanations of possible outcomes. Despite the 42 availability of these comprehensive frameworks, their practical application remains inconsistent. As the 43 internet increasingly becomes the primary source of health information for people in Europe and the 44 U.S.,^{4,5} many online resources fall short of adhering to these evidence-based standards.⁶ As a result, 45 much of the health information available online lacks the necessary accuracy and rigor, and in some 46 cases even spreads misinformation, particularly in areas such as cancer.^{7,8} This leaves individuals 47 vulnerable to receiving misleading information, which can lead to poorly informed health decisions and 48 a compromised ability to evaluate risks and benefits effectively. The rapid emergence of artificial 49 intelligence (AI) tools, particularly large language models (LLMs) such as OpenAI's ChatGPT, Google's 50 Gemini, and Mistral Al's Le Chat, has opened new possibilities for digital health communication and 51 laypeople are increasingly turning to these platforms to seek answers to health-related questions.⁹ 52 However, a critical concern remains: Can these Al-driven systems consistently provide information that 53 adheres to established guidelines for communicating patient-relevant benefits and harms, especially

54 when prompted by laypeople?

55 While previous studies have compared LLM responses to those of physicians, exploring aspects such as 56 empathy and accessibility (Ayers et al., 2023; Haver et al., 2024), others have focused on LLM accuracy 57 in specific areas such as lab test interpretation (He et al., 2024), cancer screening recommendations 58 (Huo et al., 2024), and random cancer-related queries (Pan et al., 2023), just to name a few, revealing 59 both the strengths and limitations of these models. However, in all of these studies, the interactions 60 were based on artificial prompts generated by researchers, rather than authentic inquiries from 61 laypeople. This controlled setup allowed for a systematic evaluation but did not capture the variability 62 and complexity of real-world questions relevant to patients in a chat situation.

In contrast, our research addresses a critical gap in the evaluation of LLMs by investigating how well these AI tools adhere to evidence-based guidelines when communicating about breast and prostate cancer screenings. The primary research question is: Can LLMs provide accurate, guideline-based information on the risks, benefits, and outcomes of cancer screenings, particularly when prompted by laypeople? This question is crucial, given the previous mentioned increasing reliance on AI-driven platforms for health information

69 Ultimately, previous research has focused on the general capabilities of LLMs, but our study aims to 70 determine whether these models could support informed decision-making in high-stakes medical 71 contexts, focusing on improving both user interaction and model reliability-by providing clear, 72 accurate, and evidence-based health communication. LLMs like ChatGPT, Google Gemini, and Mistral 73 AI will be tested to determine if they can be reliable sources of education, particularly in scenarios 74 where individuals seek information about cancer screening. The ultimate goal is to assess whether 75 these AI systems can be effectively integrated into healthcare systems to complement traditional health 76 communication tools, enhancing patient understanding and supporting informed health decisions 77 without replacing healthcare professionals.

- Finally, we need to evaluate the effectiveness of basic evidence-based strategies of information search.
- 79 Consequently, we study different prompting strategies on the quality of LLM responses. Specifically, we
- 80 will compare standard prompting (control group) with enhanced prompting (intervention group who
- 81 receives a brief premise for an evidence-based search) to assess how the specificity of user input affects
- 82 the adherence of LLM-generated responses to evidence-based health communication guidelines.

83 **Objective**

The primary objective is to evaluate how well LLMs, including OpenAI's ChatGPT, Google Gemini, and Mistral AI, adhere to evidence-based guidelines when responding to breast and prostate cancer screening prompts. Specifically, we aim to:

- Assess the evidence-based quality of LLM responses by evaluating the extent to which the health risk communication provided by LLMs aligns with established evidence-based guidelines. This includes assessing whether LLM-generated responses clearly communicate risks, benefits, and outcomes of breast and prostate cancer screening.
- RQ1: Is the health risk communication provided by LLMs evidence-based? The hypothesis is
 that LLMs frequently fail to meet standard criteria for evidence-based health risk
 communication, with more than 50% of responses deviating from these guidelines across
 multiple presentation criteria.
- Analyze the effect of prompt specificity on LLM response quality by determining whether more specific, well-informed prompts lead to a higher quality of evidence-based responses from LLMs. This objective focuses on how the inclusion of key decision-making information in prompts affects the clarity and accuracy of LLM outputs.
- RQ2: Does more informed prompting, particularly in terms of health decision-making
 preparation, result in better evidence-based health risk communication from LLMs? We
 hypothesize that there is a moderate to strong positive correlation between the specificity of
 the prompts and the quality of evidence-based health risk communication provided by LLMs.
- Compare the evidence-based quality of responses generated by laypeople with varying levels of informed prompting by comparing the quality of LLM responses based on prompts generated by laypeople who provide varying levels of detail and information. We will assess whether layperson-generated prompts result in more evidence-based responses than lowinformed prompts, but less so than moderately informed prompts.
- 108RQ3: Are LLM responses generated by laypeople more evidence-based than those from low-109informed prompting, but less so than moderately informed prompting? We hypothesize that110Layperson-generated prompts produce more evidence-based responses compared to low-111informed prompts, but less so than moderately informed prompts that include about 50% of112key health decision-making information.
- 4. Evaluate the impact of a minimal boosting intervention on the quality of LLM responses by assessing whether a minimal boosting intervention—where users are encouraged to provide more specific prompts by considering the consequences of their health decisions—can improve the evidence-based quality of LLM responses.
- 117RQ4: Does a minimal boosting intervention increase evidence-based responses? We118hypothesize that reminding users to consider the consequences of their choices will lead to an119increase in evidence-based responses, improving the overall adherence of LLM outputs to120guideline-based communication standards.
- 5. Test the digital native hypothesis: RQ5: Without boosting intervention, digital natives (defined
 as participants under 30 years of age) do not prompt a higher quality of LLM responses than
 people from the age of 30 years and more.

124 Trial Design

- 125 The study is divided into two phases. Phase 1 uses a content analysis design to evaluate LLM responses
- to standardized prompts. Phase 2 is a randomized between-subjects experiment with a 1:1 allocation
- 127 ratio, comparing standard prompting (control group) and enhanced prompting (intervention group).
- 128 Each group will interact with LLMs under similar conditions, but with differing levels of instruction
- 129 specificity.
- 130 Given that this study is entirely web-based, there are no onsite requirements for integrating the AI
- intervention into the trial setting. All interactions with the LLMs will occur remotely, facilitated through
 the SoSci Survey platform, hosted by the University of Potsdam. The integration of the AI systems (Open
- 133 AI ChatGPT, Google Gemini, and Mistral AI Le Chat) is managed through an API, ensuring seamless
- 134 communication between the survey platform and the LLMs.
- For offsite requirements, participants will need access to a digital device (computer, tablet) with a stable internet connection to interact with the LLMs and complete the survey.
- 137 There is no need for any physical infrastructure or on-premises installations, as the entire intervention 138 process, from user prompts to LLM responses, will be executed in the cloud through secure, encrypted
- 139 connections.

140 Methods

This protocol was developed in adherence to the Guidelines for clinical trial protocols for interventions
 involving artificial intelligence: the SPIRIT-AI extension.¹⁰

143 **Phase 1: Systematic Evaluation of LLM Responses to Predefined Prompts**

- 144 In the first phase of the study, we will systematically assess the quality of outputs generated by 145 OpenAI's ChatGPT, Google Gemini, and Mistral AI. The LLMs will respond to a set of predefined, 146 standardized English-language prompts related to BC and PC screening. These prompts will encompass 147 a range of typical patient inquiries, such as the risks and benefits of cancer screenings, the 148 interpretation of screening results, and the overall recommendation for undergoing screening. Each 149 LLM will respond to multiple iterations of the same prompts, allowing for an assessment of both 150 consistency and variability in the responses.
- 151 In total, six (decision preparation elements) times three distinct (in specificity varied) prompts will be 152 repeated 20 times across three LLMs and two screening topics, resulting in 2,160 total responses to be 153 scored. An additional scoring across six prompts (full decision preparation) will be based on nine 154 evaluation criteria of the compliance with context information standards (e.g. declaration of conflict of 155 interest). Each LLM response will be evaluated against predefined quality metrics, by independent human raters using the validated MappInfo tool for the evidence-based quality assessment of digital 156 157 health information¹¹ and a new checklist derived from the Guideline for the Development of Evidence-158 based Patient Information². This process will help identify patterns of strengths and weaknesses in how 159 LLMs communicate crucial health information.

160 Phase 2: User-Generated Prompts and Evaluation with a Minimal Boosting Intervention

161 The second phase of the study shifts from predefined prompts to user-generated prompts to explore 162 how laypeople's input affects the quality of LLM-generated health information. In this phase, 163 participants will be asked to generate their own prompts regarding breast and prostate cancer 164 screening. Participants will be randomized into two groups: 165 Control group: Participants will generate prompts with no specific guidance, reflecting a typical166 layperson's inquiry based on their own knowledge or concerns.

- 167 Intervention group: Participants will receive the minimal intervention (boosting) a brief premise for 168 an evidence-based search: "Please consider the OARS rule: You need to know your options, the 169 advantages and risks of each, and how steady they are to happen.", which implies simple instructions 170 encouraging them to consider the possible consequences of their health decisions and to provide more
- 171 specific, detailed prompts.

We will follow a similar approach to Phase 1, using predefined quality metrics to assess the responses. Furthermore, this phase will analyze whether the boosting intervention improves the overall quality of LLM responses by increasing the specificity and relevance of the user-generated prompts. Specifically, the evaluation will focus on two key aspects: (1) the proportion of evidence-based responses, measuring how often LLMs provide information aligned with established guidelines; (2) the impact of the boosting intervention, determining whether simple guidance leads to significant improvements in LLM outputs compared to unguided prompts.

179 Analysis

180 Phase 1:

Descriptive statistics will be used to summarize the quality scores of the LLM responses across the different levels of prompt specificity. The mean scores with standard deviations will be calculated for each LLM and prompt category. Additionally, the percentage of responses meeting the predefined evidence-based criteria will be computed. We test the assumption of prompt specificity and explore potential differences between LLMs with the help of ANOVA across repetitions. Two independent researchers will code the data. Interrater reliability will be assessed using Cohen's kappa coefficient to evaluate agreement between the coders. Any discrepancies will be resolved through consensus

- 188 discussions to ensure consistent and accurate evaluation.
- 189 Phase 2:

Descriptive statistics will be calculated for the demographic variables gender, age, and education, as
 well as for LLM usage frequency, prior experience, and preference for shared decision-making.

192 The primary analysis will focus on comparing the quality of LLM-generated responses across groups 193 using inference statistical methods for assessing differences between participants assigned to the 194 prompting conditions (independent variable). To evaluate the responses (the dependent variable) the 195 responses will be coded using two predefined scales to assess its adherence to evidence-based (EB) 196 health communication standards and pooled additionally (so, three dependent variables for 197 independent analyses). The coding will be based on the MappInfo tool for the evidence-based quality 198 assessment of digital health information¹¹ and the Guideline for the Development of Evidence-based 199 Patient Information². The coding will be done by two independent raters, and inter-rater reliability will 200 be assessed using Cohen's kappa. Any discrepancies between raters will be resolved through discussion 201 and consensus. The code book will be provided in the appendix of the final study.

Secondary analyses will include a statistical test based on age split (<30 vs 30+ years) on the difference in the quality of LLM responses prompted by participants of the control condition and there will be an assessment of participant preferences for informed decision-making processes and their experiences with LLMs, using descriptive statistics and mean comparisons. A subgroup analysis will explore potential differences in responses based on demographic characteristics.

- All statistical tests will be conducted at a significance level of p < .050 (and adjusted downwards
- according to Bonferroni procedure for multiple testing), and effect sizes will be calculated to determine
- 209 the meaning of findings. Results will be presented in detail with supporting tables and figures.

210 Inclusion Criteria

- 211 Phase 1, LLMs:
- 212 The inclusion criteria for selecting the LLMs in the study will be the following:
- State-of-the-Art Performance: Only LLMs that represent current, state-of-the-art models in natural language processing, such as OpenAl's ChatGPT, Google Gemini, and Mistral AI, will be considered.
- Accessibility for Public Use: The LLMs must be accessible to the general public, ensuring that
 their capabilities reflect real-world use cases and that the findings can be generalized to typical
 interactions by laypeople.
- Multidomain Knowledge: The LLMs must demonstrate the ability to handle a wide range of
 topics, including healthcare and cancer-related information, ensuring their relevance for
 answering complex, domain-specific queries.

222 Phase 2, Participants:

- Age: Participants must be 18 years or older to ensure they have the capacity to make
 informed decisions and engage meaningfully with health-related prompts.
- Language Proficiency: Participants must have proficiency in English, as the study involves
 interacting with LLMs in English and understanding health-related information presented in
 this language.
- Access to Digital Devices: Participants must have access to and be able to use digital devices
 (e.g., computers, tablets) with internet access, as the study involves generating and
 submitting prompts to LLMs online.
- 231 Geographic Location: Participants should reside in regions where access to healthcare is
- comparable to international standards, such as the U.K., to ensure that the health
- 233 information provided by LLMs is relevant and applicable to their context.

234 Exclusion Criteria

- 235 Phase 1, LLMs:
- 236 The exclusion criteria for selecting the LLMs in the study will be the following:
- Limited Access or Restricted Use: LLMs that are not publicly accessible or require proprietary
 access for specialized use will be excluded, as they do not represent general-use cases for
 laypeople.
- Domain-Specific Models: LLMs that are specifically trained or fine-tuned for niche domains
 (e.g., exclusively healthcare-specific models) will be excluded, as they do not reflect the
 broader, general-purpose models used by the public.
- Non-English Language Proficiency: LLMs that primarily operate in languages other than English
 or demonstrate limited proficiency in understanding and generating English-language
 responses will be excluded.
- 246

247 Phase 2, Participants:

248 The exclusion criteria for selecting the Participants in the study will be the following:

- Health Professionals: Individuals with professional expertise in healthcare, particularly in cancer screening or health communication, will be excluded to avoid bias and ensure that participants reflect the general lay population.
- Previous Experience with LLM Studies: Participants who have taken part in similar studies
 involving LLMs will be excluded to prevent familiarity with the technology from influencing the
 results.

255 **Procedure and material**

- 256 Phase 1:
- 257 Researchers will prompt LLMs via API and collect the responses.
- 258 Phase 2:

259 Participants will receive a brief introduction outlining the study's purpose, which involves interacting 260 with one of three LLMs [OpenAl ChatGPT (gpt-3.5-turbo)¹², Google Gemini (1.5-Flash)¹³, or Mistral Al Le Chat (mistral-large-2402)]¹⁴, all preset as a "helpful assistant" to obtain health information of ether 261 262 BC or PC screening. Following informed consent, participants will be asked to provide basic 263 demographic details such as gender, age, and education level through a questionnaire interface built 264 with SoSci Survey. They will then be given the choice to receive information about either BC or PC 265 screening. Participants will engage with the chatbot by entering their queries (prompts) through the 266 LLM's API, and the generated responses will be collected alongside the prompts for systematic analysis. 267 At the end of the session, participants will be asked about their frequency of LLM usage, their prior 268 experience with such models, and their perspectives on how an informed decision-making process 269 should ideally be conducted for them, by choosing one from four options.

- A pre-test with n=20 participants will be conducted to verify the effectiveness of the randomization procedures, ensuring balanced group assignment, the technical functionality of the survey platform and its integration with the LLM APIs. Additionally, the average completion time will be measured and potential issues related to participant burden will be identified. Feedback on user experience will be collected to address any usability concerns. Based on these findings, necessary adjustments will be made at the protocol for the main trial.
- 276 Tests and Outcomes
- 277 Primary Outcome:
- Expert scoring of how evidence-based LLM communication is (mappInfo tool in addition to a novelscore based on the guideline EB health information)
- 280 Secondary Outcome:
- 281 Self-reported use and experience with LLM; preference in shared decision-making
- 282 Sample Size
- 283 Phase 1:
- 284 There are no human participants involved.
- 285 Phase 2:
- To analyze a moderate ANOVA main effect (partial eta squared = .06) comparing two between-subjects
- conditions (with and without intervention), we are aiming for a minimum sample size of n= 237

- 288 participants. To ensure a representative sample reflecting the simplified census data of Great Britain in
- terms of sex, age, and ethnicity, we will recruit n= 300 participants from a diverse pool via Prolific¹⁵.

290 Recruitment

291 Participants will be recruited via the online platform Prolific¹⁵.

292 Assignment of Interventions

Participants will be assigned to either the control group or the intervention group via block
randomization. In the intervention group, participants will receive additional instructions designed to
improve the quality of the prompts they generate for the LLMs.

296 Allocation

- 297 To achieve a balanced distribution of participants across the study groups, we will employ a block
- randomization (1:1 allocation ratio) with the BLOCKRAND() function in SoSci Survey. The assignmentis concealed by this function.

300 Blinding

Participants and researchers will be blinded to both the assigned LLM and the type of prompting
 instructions to prevent any bias in interaction and response evaluation. Coding will happen
 independently by two researchers.

304 Data Management

Data will be collected via the SoSci Survey platform, and all datasets will be anonymized and stored securely on password-protected servers to ensure participant confidentiality. Contact details will not be collected, as Prolific—responsible for participant recruitment—operates with an anonymized data collection model. Participant demographic data, such as gender and age, will be collected separately within the study, despite these being part of the quota set by Prolific.

310 Data handling is fully anonymized. Prolific manages recruitment, while SoSci Survey, hosted by the 311 University of Potsdam, handles the questionnaires. Communication with the LLMs is facilitated through 312 an API within SoSci Survey, and LLM providers do not have access to the study data. Payment processing 313 is managed entirely by prolific.co, and no financial data is collected or stored on our end. Additionally, 314 no names, addresses, birth dates, or IP addresses will be recorded. We will not record the recruitment 315 IDs generated by prolific.co, and due to the large number of simultaneous participants and the 316 variability in time between recruitment and survey completion, it will not be feasible to link 317 questionnaire responses with recruitment IDs.

- The anonymized research data will initially be stored on a password-protected account under the control of the project lead on the SoSci Survey server (hosted by the University of Potsdam). For further
- 320 analysis, the data will be transferred to password-protected computers under the supervision of project
- 321 team members at the Harding Center for Risk Literacy. Prolific will not have access to the research data
- 322 at any point.

323 Statistical Methods

324 Data will be analyzed using descriptive statistics and inferential statistical tests, including t-tests and

- ANOVA for group comparisons, and linear regression models for more detailed analyses of prompt
- 326 specificity effects. All statistical tests will be conducted at a significance level of p<0.05, and effect sizes
- 327 will be calculated to determine the practical significance of findings.

328 Harms

No physical or psychological risks are anticipated for participants. Anticipated survey completion time is six minutes. Participation is entirely voluntary, and participants can withdraw at any time.

Errors of the used LLMs will be identified through content analysis conducted by independent human raters using predefined quality metrics, and categorized based on their nature and impact on the reliability of the information provided. The errors will then be analyzed to determine patterns of LLM performance issues. If errors are not analyzed in specific instances, it will be due to limitations in the scope of the study, such as focusing primarily on guideline adherence rather than linguistic or technical issues outside the study's objectives.

337 Monitoring

338 The study will be monitored by the research team at the Harding Center for Risk Literacy. Regular audits

339 will be conducted to ensure compliance with the study protocol and data management procedures.

340 Ethics and Dissemination

341 Ethics approval was obtained from the University of Potsdam's Ethical Committee (Approval No.

342 52/2024) on August 29, 2024. The complete study protocol is publicly available on the website of the

343 Harding Center (https://www.hardingcenter.de/de/forschung/projekt-eb-llm). Findings from the study

will be disseminated through academic publications, conference presentations, and open-access
 databases to contribute to the field of digital health communication. A de-identified, aggregate-level

data will be made available upon reasonable request to qualified researchers who agree to comply with

347 ethical guidelines for data sharing and usage.

348 Protocol Amendments

All amendments to the protocol will be submitted to the ethical committee for review and approval.
 Any major changes will be communicated to participants and will be listed, along with justifications, in

a new version of the study protocol and the final study publication.

352 Consent

Participants will provide informed consent electronically prior to participating in the study. The consent
 form includes detailed information about the study, participant rights, and data protection measures.

355 Confidentiality

All participant data will be anonymized, and no personally identifiable information will be collected or stored. Data will be stored securely, and access will be restricted to the research team.

358 Funding and Conflicts of Interest

359 This study will not receive any external funding. There are no financial conflicts of interest to declare.

- Furthermore, we confirm that neither the research team nor any individual involved in this study will receive any monetary or personal benefit from the engagement of prolific for participant recruitment.
- 362 The commissioning of funds for various studies using Prolific is managed through the relevant
- The commissioning of funds for various studies using Promite is managed through the
- 363 department for procurement of the University of Potsdam.

364 Role of Study Sponsor and Funders

365 As this study is not funded by any external sponsor, there is no external influence on the study design,

- data collection, management, analysis, interpretation of data, or the writing of the final report. The
- 367 decision to submit the report for publication rests solely with the research team of the Harding Center.

The research will be conducted independently, without involvement from any third-party sponsor or funder.

370 Composition, Roles, and Responsibilities

- The study will be coordinated by the research team at the Harding Center, with oversight by the project lead Dr. Felix G. Rebitschek. Given the nature of this trial and the lack of external funding, there is no
- 373 steering committee or endpoint adjudication committee involved. Data management will be handled
- by the research team, ensuring compliance with data privacy regulations and ethical standards. There
- is no need for a separate data monitoring committee, as the study presents minimal risk and involves
- anonymized, non-invasive interactions with AI-based language models.

377 Contribution

- 378 Christoph Wilhelm (CW) and Dr. Felix G. Rebitschek (FGR) were responsible for the conceptualization
- and development of the methodology. CW wrote this protocol. CW is the guarantor of the mauscript.
- 380 FGR contributed equaly, provided key resources, and oversaw the project administration. He reviewed,
- edited, and supervised this protocol. Both autors significantly contributied to the writing, reviewing,
- and editing of this manuscript.

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