Contemporary Clinical Trials Communications 3 (2016) 32–38

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

A pragmatic randomized trial comparing tablet computer informed consent to traditional paper-based methods for an osteoporosis study

A.H. Warriner [a, *], P.J. Foster [b], A. Mudano [b], N.C. Wright [c], M.E. Melton [b], S.E. Sattui [b], W. Calmbach [d], J.R. Curtis [b], M. Kilgore [e], C.E. Lewis [f], W. Pace [g], K.G. Saag [b]

[a] Division of Endocrinology, Diabetes, and Metabolism, University of Alabama at Birmingham, United States
[b] Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham, United States
[c] Department of Epidemiology, University of Alabama at Birmingham, United States
[d] Department of Family & Community Medicine, University of Texas Health Science Center at San Antonio, United States
[e] Department of Health Care Organization and Policy, University of Alabama at Birmingham, United States
[f] Division of Preventive Medicine, University of Alabama at Birmingham, United States
[g] American Academy of Family Physicians National Research Network, United States

ARTICLE INFO

Article history:
Received 30 September 2015
Accepted 11 February 2016
Available online 17 February 2016

Keywords:
Informed consent
Pragmatic clinical trials
Osteoporosis

ABSTRACT

Objective: Methods to improve informed consent efficiency and effectiveness are needed for pragmatic clinical trials. We compared informed consent using a tablet computer to a paper approach to assess comprehension and satisfaction of patients and clinic staff for a future osteoporosis clinical trial.
Methods: Nine community-based practices identified and recruited patients to compare the informed consent processes (tablet vs. paper) in a mock osteoporosis clinical trial. The tablet informed consent included an animation summarizing the trial, complete informed consent document, and questions to assess and reinforce comprehension of the study. Participants were women age ≥55 years with ≥1 year of alendronate use. We surveyed participants to assess comprehension and satisfaction and office staff for satisfaction and perceived time demands.
Results: The nine practices enrolled 33 participants. There was not a significant difference in comprehension between the tablet vs. paper informed consent [mean (SD) tablet: 12.2 (1.0) vs. paper: 11.4 (1.7)]. Office staff preferred the tablet to the paper informed consent for identifying potential study participants (two-sided t-test $p = 0.02$) despite an increased perceived time spent to complete the tablet process [tablet: 28.3 min (SD 16.3) vs. paper: 19.0 min (SD 6.9); $p = 0.08$].
Conclusions: Although, there were no significant differences in participant satisfaction and comprehension with the tablet informed consent compared to a paper informed consent, patients and office staff trended towards greater satisfaction with the tablet informed consent. Larger studies are needed to further evaluate the utility of electronic informed consent in pragmatic clinical trials.

1. Introduction

Pragmatic clinical trials (PCTs) evaluate the real world effectiveness of interventions in the general population rather than the more homogenous populations used in traditional randomized controlled trials [1,2]. Including participants from diverse community settings is needed to maximize the generalizability typically required of PCTs. However, ensuring efficient and effective participant informed consent represents a challenging component of PCTs in settings where the conduct of research is not a primary function [3–6].

Due to time and resource requirements, the informed consent process is a barrier to performing PCTs in many practice settings [7,8]. This is particularly true for many community practices; especially among practices not well-versed in research procedures or without dedicated research staff. The traditional informed consent process using a paper form requires dedicated personnel to explain the study, clarify details, answer questions, and guide patients through the informed consent process. This requires time

* Corresponding author. The University of Alabama at Birmingham, Division of Endocrinology, Diabetes and Metabolism, 702 Faculty Office Tower, 510 20th Street South, Birmingham, AL 35294, United States.
E-mail address: awarriner@uabmc.edu (A.H. Warriner).

http://dx.doi.org/10.1016/j.conctc.2016.02.003

and effort from staff members and clinicians who may be in a busy practice setting focused on high throughput clinical care.

As recognized by the Office of Human Research Protections, there are also concerns about whether the current informed consent process leads to fully informed study participants [9]. Thus, there is a need to improve the efficiency of the informed consent process and improve patient comprehension of clinical research benefits and risks [10,11]. Electronic tools that provide audiovisual enhancements to improve patient comprehension can potentially reduce time demands of busy office staff, might alleviate some of the informed consent barriers, and could improve comprehension, but they have not been shown to have clear benefit in all studies [11–16].

To address these evidence gaps in the informed consent process, we developed a patient self-administered tablet informed consent tool and conducted a mock study of a future osteoporosis PCT of bisphosphonate discontinuation versus continuation. We compared patient comprehension and satisfaction and provider satisfaction with the electronic informed consent process compared to traditional paper informed consent process in community practices.

2. Methods

2.1. Overview

We identified nine community-based practices and asked them to enroll three participants per informed consent process type (tablet informed consent process versus traditional paper informed consent process). In collaboration with a software developer experienced in direct-to-patient studies (Mytrus, Inc, San Francisco), we developed an interactive tablet informed consent tool that included an animated audiovisual summary of a future PCT, the complete informed consent document, and comprehensive multiple choice questions with feedback to assess and reinforce the key study consent elements. We surveyed participants' comprehension and satisfaction immediately following both informed consent processes. We also surveyed practice staff to assess satisfaction and perceived time demands following each type of informed consent process and again at the end of the study to compare the two processes. All study procedures were approved by the University of Alabama at Birmingham Institutional Review Board.

The mock study used for this evaluation of the informed consent processes was a future osteoporosis PCT. The future study does not include the use of any new treatments or interventions and, consistent with PCT methodology, the inclusion criteria are minimal. Women enrolling in the mock study were required to provide social security numbers, which would be used to link to the participants' administrative claims data in the future PCT.

2.2. Site recruitment and selection strategy

We identified community-based practice sites (n = 9: n = 7 “solo”, n = 2 “group”) from the American Academy of Family Physicians National Research Network (AAFP NRN), the Alabama Practice Based Research Network (APBRN), and the South Texas Ambulatory Research Network (STARNet). We selected a convenience sample of eligible sites based on their desire to participate, their perceived ability to recruit a sufficient number of eligible participants, and resources available. While the AAFP NRN, APBRN, and STARNet membership differed slightly in their demographic characteristics, members of practice based research networks (PBRNs) have been shown to be representative of community practices at large [17]. Practices were randomized to start with either the tablet informed consent process or the paper informed consent process and then were switched to the alternate informed consent process after completing 3 participant enrollments, for a total of 6 participants per practice in order to best assess each clinic's satisfaction with the both methods.

2.3. Patient recruitment and informed consent process

Practice sites initially identified eligible participants from their specific practice based on the inclusion criteria of the future osteoporosis study, i.e. ≥55 years old and ≥1 year alendronate use. When women presented to the clinic, if they were willing to consider participation, they were first provided a paper screening form, which included 3 questions: (1) Are you currently taking Alendronate (Fosamax® or Binosto™)?, (2) If yes, have you been taking Alendronate (Fosamax® or Binosto™) for 1 or more years?, and, (3) Are you willing to use a tablet computer to give and receive medical information? If the women answered “yes” to all three questions, the clinic staff would then provide them with either the tablet or paper informed consent. We included the requirement of willingness to use a tablet computer in the screening questionnaire in an effort to include women with similar comfort levels with technology in the two informed consent study groups.

2.4. Electronic informed consent process

The tablet informed consent tool initially presented screening questions for participants to complete, first re-verifying the basic inclusion criteria, including the participant's age and use of alendronate for at least 1 year. If the inclusion criteria were confirmed, the tool then presented an audiovisual description of the research study using an animated video with avatars describing the important details of the study, including the randomization process and the potential risks and benefits associated with each arm of the osteoporosis PCT. Participants were provided with earbuds to assure only they could hear the audio and a stylus to help navigate the tablet touchscreen. After the animated video, a complete IRB-approved informed consent document was presented on the tool. The informed consent also contained seven comprehension multiple choice questions. The questions focused on the key components of informed consent: study purpose, randomization, medication risks, medication benefits, withdrawal from the study, patient compensation, and confidentiality. If the participant did not answer a question correctly, she was provided a pertinent “Hint”. The participant was also offered the option to return to the informed consent document to review the related information in greater detail prior to having the question re-asked. There was no limit to the number of attempts a participant had to answer a question correctly but questions must be answered correctly before the participant could continue in the informed consent document. After completely reviewing the informed consent document and answering the questions correctly, the participant was asked to provide her social security number and date of birth and was then prompted to sign the informed consent document using the touch screen (with the provided stylus or her finger). After completion of the participant component, the staff then verified all inclusion/exclusion criteria and co-signed the informed consent document. Participants were then asked to complete the brief comprehension and satisfaction assessment (see below).

The number of questions, their content, and how many tries participants were given to answer questions correctly within the tablet tool was under the investigators' control. A summary report from the tablet tool, which included any questions which were answered wrong, was provided in real time for review by the enrolling practice staff before co-signing the informed consent. After the clinic staff signed off on the informed consent, dynamic