# Right For Me: Protocol for a cluster randomised trial of two interventions for facilitating shared decision-making about contraceptive methods

Study Objectives, Research Questions, Hypotheses, and Analytic Plan

| Objectives | | Research Questions | Hypotheses | Analytic Plan |
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| **The first objective of this study is to evaluate the effect of (1) a video + prompt card that encourage patients to ask three specific questions in the health care visit, and (2) decision aids + training for health care providers in their use, on shared decision-making about contraceptive methods in the health care visit.** | 1 | Does implementing the video + prompt card increase the rate of shared decision-making about contraceptive methods compared to usual care? | We hypothesise that implementing the video + prompt card will increase the rate of shared decision-making about contraceptive methods compared to usual care. | The primary outcome for the analysis is shared decision-making about contraceptive methods, a binary variable. To account for the cluster randomized design, the analysis will use random effects logistic regression for binary outcome variables as implemented in SAS PROC GLIMMIX, with a random intercept for clinic. The analysis will adjust for the clinic-level pre-existing rate of shared decision-making and any other participant characteristics that differ across trial arms. Contrasts between group rates will be performed using the model results to address research questions 1-3. |
| | 2 | Does implementing the decision aids + training increase the rate of shared decision-making about contraceptive methods compared to usual care? | We hypothesise that implementing the decision aids + training will increase the rate of shared decision-making about contraceptive methods compared to usual care. | |
| | 3 | Does implementing the video + prompt card and the decision aids + training result in greater increases in the rate of shared decision-making about contraceptive methods compared to usual care than implementing either of the interventions alone? | We hypothesise that implementing the video + prompt card and the decision aids + training will result in greater increases in the rate of shared decision-making about contraceptive methods compared to usual care than implementing the video + prompt card alone or the decision aids + training alone. | |
| | 4 | What patient characteristics and other factors modify the effect of implementing the interventions on the rate of shared decision-making about contraceptive methods? | This heterogeneity of treatment effects (HTE) analysis is exploratory (i.e., hypothesis generating) and thus no a priori hypotheses for this research question have been developed. | We will use the same modelling techniques to assess modifiers of the shared decision-making rate effects seen for research questions 1-3 by fitting interaction terms with the intervention group variables. The modifiers considered will be age, gender identity, health insurance, health literacy, |

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| | | | | educational attainment, ethnicity, race, exposure to interventions (three variables), exposure to other interventions (one variable), and pre-existing shared decision-making.<br><br>In reporting the modifier analyses, p-values will be shown adjusted for multiple comparisons. |
| **The second objective is to evaluate the effect of these interventions on several other outcomes (see Outcomes and Measures).** | | For each of the secondary outcomes: | | |
| | 5 | Does implementing the video + prompt card increase or decrease (as relevant) the [rate/level] of [secondary outcome] compared to usual care? | We hypothesise that implementing the video + prompt card will increase the rate of conversation about contraception, optimal satisfaction with the conversation about contraception, optimal values concordance of intended contraceptive method(s), use of intended contraceptive method(s), optimal adherence to contraceptive method(s) used, optimal satisfaction with contraceptive method(s) used; decrease the level of decision regret; and decrease the rate of unintended pregnancy (pregnancy timing preferences), unintended pregnancy (pregnancy seeking), and unwelcome pregnancy compared to usual care.<br><br>Analyses pertaining to the secondary outcomes of intended contraceptive method(s), intention to use a highly effective contraceptive method, contraceptive method(s) used, and use of a highly effective contraceptive method are exploratory and thus no a priori hypotheses for these secondary outcomes have been developed. | We will conduct separate analyses to answer these research questions for each of the 14 secondary outcomes.<br><br>We will use a random effects regression for either categorical or continuous outcomes with a random intercept for clinic to account for clustering. The analysis will adjust for participant characteristics that differ across trial arms. Contrasts between group rates or means will be performed as with the primary outcome.<br><br>For analyses pertaining to the secondary outcome, *Conversation About Contraception*, we will use three denominators: (a) all participants, (b) all participants except those not at risk of unintended pregnancy, and (c) all participants except those not at risk of pregnancy and those who reported that they did not want or need to talk about contraception. |
| | 6 | Does implementing the decision aids + training increase or decrease (as relevant) the [rate/level] of [secondary outcome] compared to usual care? | We hypothesise that implementing the decision aids + training will increase the rate of conversation about contraception, optimal satisfaction with the conversation about contraception, optimal values concordance of intended contraceptive method(s), use of intended contraceptive method(s), optimal adherence to contraceptive method(s) used, optimal satisfaction with contraceptive method(s) used; decrease the level of decision regret; and decrease the rate of unintended pregnancy (pregnancy timing preferences), unintended pregnancy (pregnancy seeking), and unwelcome pregnancy compared | |

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| | | | to usual care.<br><br>Analyses pertaining to the secondary outcomes of intended contraceptive method(s), intention to use a highly effective contraceptive method, contraceptive method(s) used, and use of a highly effective contraceptive method are exploratory and thus no a priori hypotheses for these secondary outcomes have been developed. | For analyses pertaining to the secondary outcome, *Intended Contraceptive Method(s)*, we will use three denominators: (a) all participants, (b) all participants except those not at risk of unintended pregnancy, and (c) all participants except those not at risk of unintended pregnancy and those who reported that they did not want or need to use a birth control method.<br><br>For analysis pertaining to the secondary outcome, *Intention to Use a Highly Effective Contraceptive Method*, we will use three denominators: (a) all participants, (b) all participants except those not at risk of unintended pregnancy, and (c) all participants except those not at risk of unintended pregnancy and those who reported that they did not want or need to use a birth control method.<br><br>In reporting the secondary analyses, p-values will be shown adjusted for multiple comparisons. |
| | 7 | Does implementing the video + prompt card and the decision aids + training result in greater increases or decreases (as relevant) in the [rate/level of [secondary outcome] compared to usual care than implementing either of the interventions alone? | We hypothesise that implementing the video + prompt card and the decision aids + training will result in greater increases in the rate of conversation about contraception, optimal satisfaction with the conversation about contraception, optimal values concordance of intended contraceptive method(s), use of intended contraceptive method(s), optimal adherence to contraceptive method(s) used, optimal satisfaction with contraceptive method(s) used; greater decreases in the level of decision regret; and greater decreases in the rate of unintended pregnancy (pregnancy timing preferences), unintended pregnancy (pregnancy seeking), and unwelcome pregnancy compared to usual care than implementing the video + prompt card alone or the decision aids + training alone.<br><br>Analyses pertaining to the secondary outcomes of intended contraceptive method(s), intention to use a highly effective contraceptive method, contraceptive method(s) used, and use of a highly effective contraceptive method are exploratory and thus no a priori hypotheses for these secondary outcomes have been developed. | |
| **The third objective is to evaluate the (1) feasibility of the interventions (operationalised as rates of patient exposure to the interventions) and (2) their acceptability to patients.** | 8 | Of participants receiving care in a trial arm implementing the video + prompt card, what proportion report having watched the whole video? | We hypothesise that, of participants receiving care in a trial arm implementing the video + prompt card, at least 70% will report having watched the whole video. | Proportions and confidence intervals will be reported both separately by clinic and for all clinics as a whole. |
| | 9 | Of participants receiving care in a trial arm implementing the video + prompt card, what proportion report having received the prompt card? | We hypothesise that, of participants receiving care in a trial arm implementing the video + prompt card, at least 70% will report having received the prompt card. | |

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| | 10 | Of participants receiving care in a trial arm implementing the decision aids + training, what proportion report having used a decision aid together with a health care provider? | We hypothesise that, of participants receiving care in a trial arm implementing the decision aids + training, at least 70% will report having used a decision aid together with a health care provider. | |
| | 11 | Is the proportion of participants who report having watched the whole video higher among those receiving care in a trial arm implementing both the video + prompt card and decision aids + training than in a trial arm implementing only the video + prompt card? | We hypothesise that the proportion of participants who report having watched the whole video will be higher among those receiving care in a trial arm implementing both the video + prompt card and decision aids + training than in a trial arm implementing only the video + prompt card. | We will conduct three analyses. To account for the cluster randomized design, the analyses will use random effects logistic regression, as described above. The analyses will adjust for any participant characteristics that differ across trial arms. In reporting analyses, p-values will be shown adjusted for multiple comparisons. |
| | 12 | Is the proportion of participants who report having received the prompt card higher among those receiving care in a trial arm implementing both the video + prompt card and decision aids + training than in a trial arm implementing only the video + prompt card? | We hypothesise that the proportion of participants who report having received the prompt card will be higher among those receiving care in a trial arm implementing both the video + prompt card and decision aids + training than in a trial arm implementing only the video + prompt card. | |
| | 13 | Is the proportion of participants who report having used a decision aid together with a health care provider higher among those receiving care in a trial arm implementing both the decision aids + training and video + prompt card than in a trial arm implementing only the decision aids + training? | We hypothesise that the proportion of participants who report having used a decision aid together with a health care provider will be higher among those receiving care in a trial arm implementing both the decision aids + training and video + prompt card than in a trial arm implementing only the decision aids + training. | |
| | 14 | What proportion of participants who report having watched the whole video would recommend it to a friend? | We hypothesise that a majority of participants who report having watched the whole video would recommend it to a friend. | Proportions and confidence intervals will be reported both separately by clinic and for all clinics as a whole. |

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| | 15 | What proportion of participants who report having received the prompt card would recommend it to a friend? | We hypothesise that a majority of participants who report having received the prompt card would recommend it to a friend. | |
| | 16 | What proportion of participants who report having used a decision aid together with a health care provider would recommend it to a friend? | We hypothesise that a majority of participants who report having used a decision aid together with a health care provider would recommend it to a friend. | |
| | 17 | Is the proportion of participants who would recommend the video to a friend higher among those receiving care in a trial arm implementing both the video + prompt card and decision aids + training than in a trial arm implementing only the video + prompt card? | We hypothesise that the proportion of participants who would recommend the video to a friend will be higher among those receiving care in a trial arm implementing both the video + prompt card and decision aids + training than in a trial arm implementing only the video + prompt card. | We will conduct three analyses. To account for the cluster randomized design, the analyses will use random effects logistic regression, as described above. The analyses will adjust for any participant characteristics that differ across trial arms. In reporting analyses, p-values will be shown adjusted for multiple comparisons. |
| | 18 | Is the proportion of participants who would recommend the prompt card to a friend higher among those receiving care in a trial arm implementing both the video + prompt card and decision aids + training than in a trial arm implementing only the video + prompt card? | We hypothesise that the proportion of participants who would recommend the prompt card to a friend will be higher among those receiving care in a trial arm implementing both the video + prompt card and decision aids + training than in a trial arm implementing only the video + prompt card. | |
| | 19 | Is the proportion of participants who would recommend the decision aids to a friend higher among those receiving care in a trial arm implementing both the decision aids + training and video + prompt card than in a trial arm implementing only the decision aids + training? | We hypothesise that the proportion of participants who would recommend the decision aids to a friend will be higher among those receiving care in a trial arm implementing both the decision aids + training and video + prompt card than in a trial arm implementing only the decision aids + training. | |