

**Randomized Efficacy Trial of Early Preconception Counseling for Diabetic Teens
(READY-Girls)**

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ABSTRACT

*Objective-*To develop and assess the feasibility of an early preconception counseling program for adolescents called *READY-Girls*. .

Research Design and Methods- Fifty-three adolescent females with T1D between 16-19.9yrs were randomized into: CD, book, or control/standard care, and given one comprehensive session. Outcomes were assessed at baseline, immediately-after, and at 3-months.

Results- Teens that received the CD and book significantly ($p \leq .05$) improved in knowledge, perceived benefits of PC and of using effective family planning, and perceived more support with reproductive health issues which were sustained over three months.

Conclusions- Clinical feasibility of the program was demonstrated. Both the CD and book appeared to be efficacious formats for short term. Future studies should examine repeated boosters of both CD and book. They are not to replace, but reinforce and supplement health professional education.

Risks of reproductive complications can be significantly reduced through preconception counseling (PC)(1-3). Despite recommendations by the American Diabetes Association (ADA) that all women of child-bearing potential receive PC(4), most diabetic women do not receive PC, and two-thirds continue to have unplanned pregnancies(5-8). In a previous study, we found that adolescent diabetic females reported unsafe sexual practices and were unaware of the risks of diabetes and pregnancy and of the availability of PC(9). This study developed a fundamental PC program (READY-Girl) specifically tailored for diabetic adolescents; explored clinical feasibility, short-term (3-month) program efficacy, and the most effective delivery format.

RESEARCH DESIGN AND METHODS

“Reproductive-health Education and Awareness of Diabetes in Youth for Girls” (*READY-Girls*)(10) is a self-instructional developmentally-appropriate, evidence-based CD-ROM and book(4-9,11). Content was validated through resource-identification, formal consensus of experts(12,13), and a focus group of diabetic teens for content/language/presentation(12).

Embedded within the STAR (stop-think-act-reflect) decision-making framework(13,14) and the Expanded Health Belief Model (EHBM)(15-19,20,21), *READY-Girls* presents the effects of diabetes on reproductive-health/puberty/sexuality/pregnancy, the benefits of PC, and practices skills for decision-making/communication.

In a randomized-controlled, repeated-measures feasibility study, subjects were randomized into one of three protocols: CD (n=17), book (n=16), or control/standard care (n=20). Both intervention groups (CD or book) received one comprehensive session of the program prior to routine diabetes clinics.

Subjects were seen only at their visits. Process evaluation included timing, effort, ease-of-use and satisfaction. Outcome measures evaluated reproductive-health and PC knowledge, beliefs (EHBM dimensions: susceptibility, severity, benefits, barriers, self-efficacy, motivational cues, social support), intention and behaviors (of seeking PC and using effective family-planning); and metabolic control. Each dimension was a composite score (higher scores=greater levels of the construct). Outcomes were assessed at baseline, immediate-post intervention (post-test-1), and at 3-month follow-up (post-test-2) by paper-and-pencil self-administered questionnaires (Cronbach’s alpha=.65-.83) based on a standard validated interview-schedule(22-23). Data were analyzed using descriptive statistics, group comparative analyses and repeated measures mixed-modeling-methods(24). Post-hoc comparisons explored group-main-effects and group-by-time interactions.

Fifty-three out of a possible 60 females with T1D between 16-19.9yrs (mean=17.4yrs) from a diabetes clinic self-selected to participate. Their mean duration-of-illness was 9.9yrs, 64% were \geq middle income, 4.4% African American, 32% were sexually active. Consent was obtained from teens >18yrs, or consent/assent from parents and teens < 18yrs.

RESULTS

Both CD and book took less than 1-hour to review (average time: CD=47.0 \pm 15min. versus book=34.3 \pm 8.4min.). Both were rated (94%-100%) as having helpful, easy-to-understand information.

Results for knowledge, beliefs (benefits, barriers), social support, intentions, and metabolic control (A1C) are illustrated in Figure 1. From baseline to immediately-post intervention (post-test-1), compared to controls, teens that received the program

significantly improved in knowledge (CD:42.7%, $p<.001$; book:45.3%, $p<.001$; control:12.6%, $p=.38$), and sustained effects at the 3-month follow-up (post-test-2) (CD: $p=.96$; book: $p=.71$). Controls increased at 3-months (19.0%, $p=.004$). A significant time-by-group interaction was found for knowledge [$F(2,40.1)=3.77$, $p=.032$]

There were significant group-by-time effects for beliefs (benefits, barriers) {benefits [$F(2,40.1)=3.48$, $p=.040$]; barriers [$F(2,40)=4.82$, $p=.013$]. From baseline to post-test-1, teens that received the program significantly improved in benefits [CD:12.3% ($p=.05$); book:12.7% ($p=.04$); control ($p=.44$)]. Effects were sustained at post-test-2 (CD: $p=.19$; book: $p=.49$), while controls significantly decreased (-6.2%, $p=.03$). For barriers, the only significant change from baseline to post-test-1 was controls (24.0%, $p=.02$). At 3-months, CD had significantly decreased (-20.5%, $p=.04$), book had significantly increased (21.8% $p=.03$), and controls had no significant change ($p=.90$). No significant group-by-time or group effects were observed for susceptibility, severity, or self-efficacy.

Social support had significant group effects [$F(2,39.4)=3.37$, $p=.045$]. Both intervention groups showed a significant increase from baseline to immediate post-test-1 (CD:11.5%, $p=.007$; book:15.6%, $p<.001$; control $p=.98$), with effects sustained at post-test-2.

Intention to seek PC and use effective family planning had a significant time effect [$F(1,37)=5.75$, $p=.022$] from baseline to post-test-1. Only book had a significant decrease from post-test-1 to post-test-2 (-13.0%, $p=.02$), while the CD and controls sustained their modest increases. Actual behaviors (seeking PC and using effective family planning) had no significant group-by-time effect.

A1C had no significant group differences from baseline to 3-months follow-up

($p=.134$). However, CD had an average decrease of -1%, compared to book's average increase of 2%, and controls average increase of 8%.

CONCLUSIONS

Program evaluation(25) was completed over a 3-month follow-up. Clinical feasibility of the *READY-Girl's* program was demonstrated, and both interventions (CD and book) appeared to be efficacious formats.

Compared to controls, teens that received the program improved in knowledge, perceived benefits of PC and of using effective family planning, and perceived more support with regards to reproductive health issues, preventing an unplanned pregnancy, and seeking PC. These findings are in accordance with the EHB(20,21).

CD and control groups identified greater barriers. CD group had diminished barriers at 3-months, perhaps because the CD had an interactive individualized problem-solving exercise.

Intention to use effective family planning and to seek PC increased in all three groups. Actual behaviors had no significant group-by-time effect perhaps because of the short time frame of 3-months.

Although no significant group effect, the percent change in A1C from baseline to 3-month appears clinically meaningful; the CD group decreased by -1% (indicating improved control), while the control group had a percent change of 8%. Future studies should include: younger, larger, more diverse sample sizes; longer-term outcomes; beginning at puberty, the intervention should be targeted to teens and include their parents; and CD-ROM and book could be used sequentially and the information repeated for reinforcement. *READY-Girls* appears to be an efficacious early-intervention program for teens. *READY-Girls* is not to replace, but supplement health-professional education(12). Both CD-ROM and book(10) are designed to be easily

integrated into clinical settings. Similar programs have been successful for other health behaviors(12,26-28). Programs like READY-Girls could potentially set new standards of practice and be an integral part of diabetic adolescent education to empower teens in making informed decisions regarding their reproductive-health(12).

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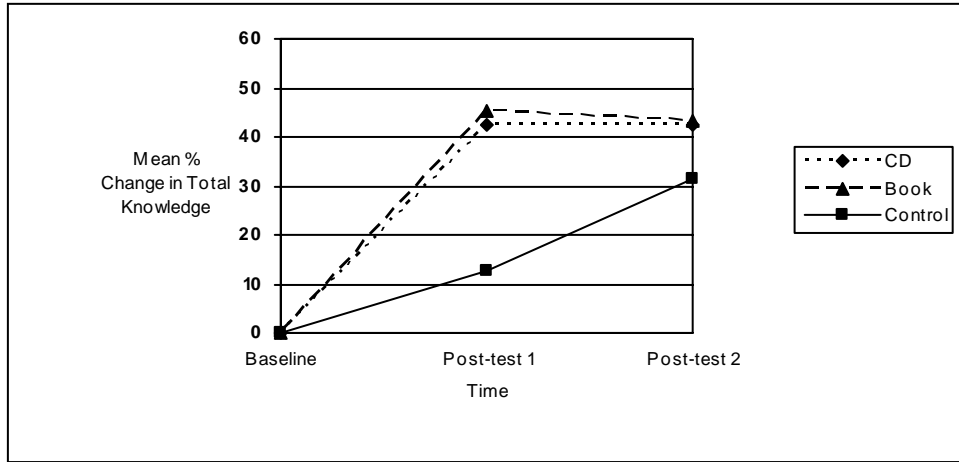
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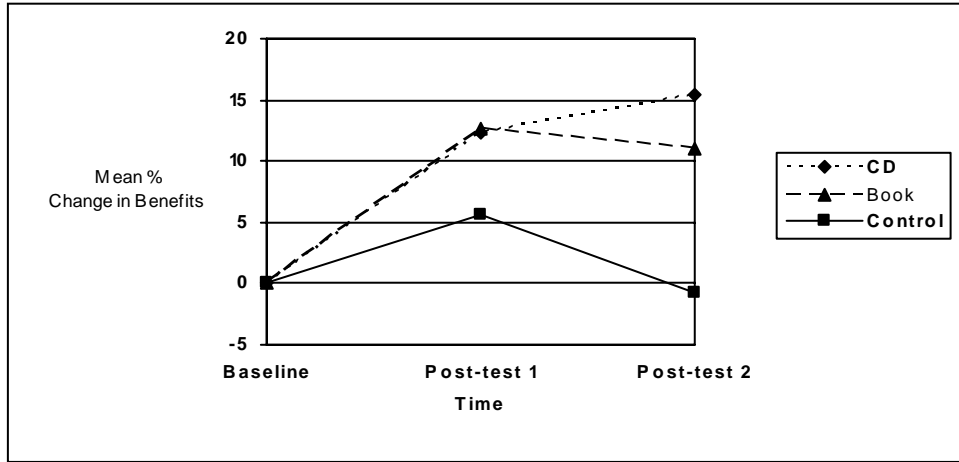
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Figure 1 --- Group response profiles for outcome variables expressed as a percentage change from baseline values to follow-up post-test values: (A) Total knowledge (diabetes-pregnancy, -contraception, -sexuality, and -family planning) a summation of 25 dichotomous items (correct = 1, incorrect = 0, % correct); (B) Perceived benefits of seeking PC and using family planning, a summation of 5 Likert-type items (possible range = 5-25); (C) Perceived barriers to seeking PC and using family planning, a summation score of 5 Likert-type items (possible range = 5-25); (D) Perceived availability of social support (emotional, informational, and instrumental) with PC and family planning, a summation of 8 Likert-type items (possible range = 8-40); (E) Intention to seek PC and use effective family planning, a summation of 3 items (1 = unlikely to 7 = likely; possible range = 3-21); and (F) A1C (metabolic control) was measured by the home Accu-Base HbA1c Sample Collection Kit. Blood finger stick assays were analyzed in Vanderbilt Pathology Lab Services, Vanderbilt University Medical Center using a high-performance liquid chromatography analyzer (ion-exchange method) (Bio-Rad Diamat HPLC, Hercules, CA). The reference range for the Diamat HPLC was 4.2 % to 5.8%. Baseline = pretest; post-test 1 = immediate-post intervention; and post-test 2 = 3-month follow up. Three-month analyses were conducted on completed longitudinal data from 47 subjects [16 (34%) CD, 16 (34%) book, and 15 (32%) control] controlling for sexual activity and age as covariates.

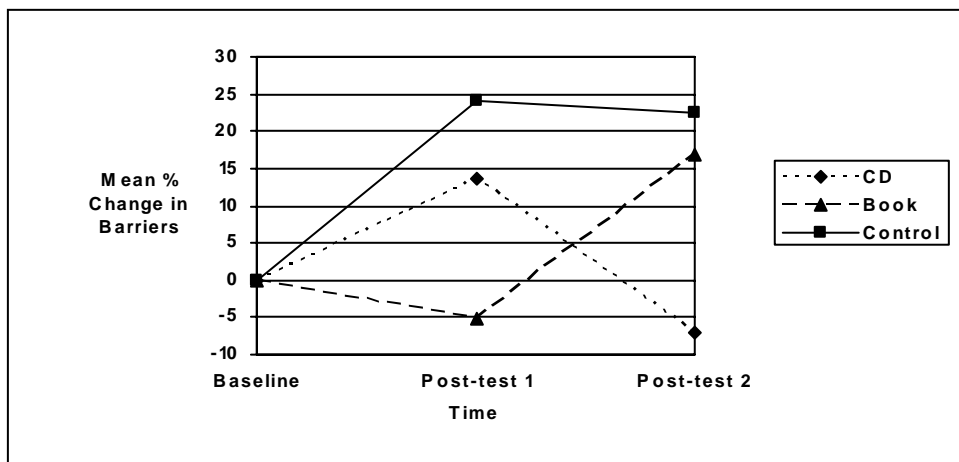
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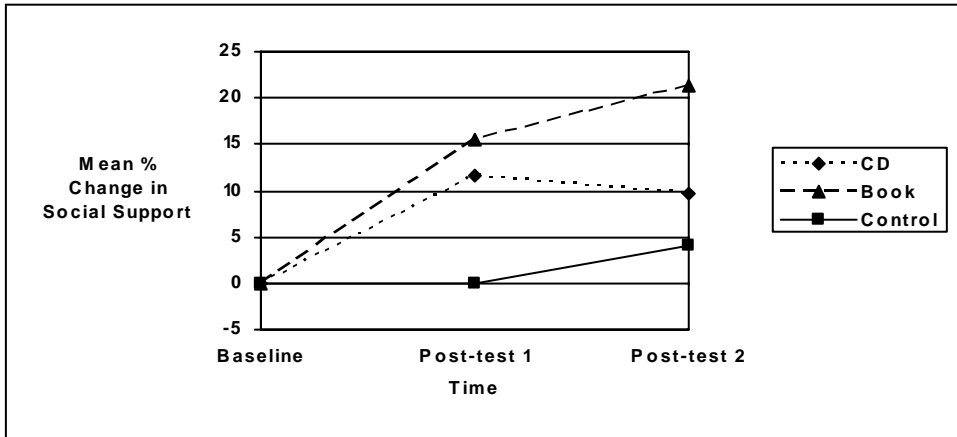
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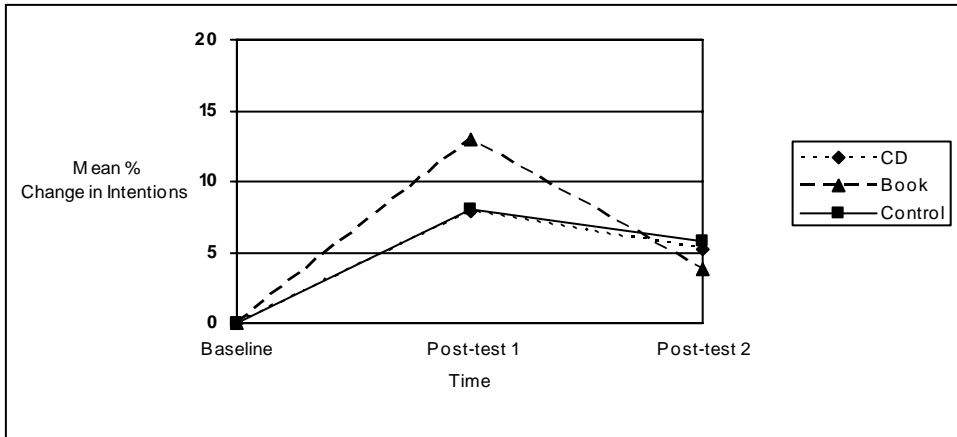
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D



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