

A Comparison of Live Counseling with a Web-Based Lifestyle and Medication Intervention to Reduce Coronary Heart Disease Risk: A Randomized Clinical Trial.

BACKGROUND:

- A healthy lifestyle and medication adherence can significantly reduce risk of CHD.
- Clinicians lack skills and resources to provide lifestyle and medication management programs for coronary heart disease.

OBJECTIVE

- To assess the effectiveness, acceptability, and cost-effectiveness of a combined lifestyle and medication intervention to reduce CHD risk offered in counselor-delivered and web-based formats.

METHODS

- **Design:** 5 diverse family medicine practices, randomized parallel trial; Duration: 12 months
- **Inclusion criteria:** Patients were aged 35-79 years, with no CVD and with moderate to high risk for CHD as shown by a 10-year Framingham risk score (FRS) $\geq 10\%$.
- **Exclusion criteria:** Known coronary heart disease
- **Primary outcome measure:** The primary effectiveness measure was within-group change at 4 month follow-up
- **Secondary outcome measures:** Secondary effectiveness outcomes included between group change in FRS and change in dietary intake, physical activity, smoking, medications adherence, blood pressure, blood lipid levels, and health related quality of life. An analysis of moderators of outcomes was planned.
- 385 patients
 - 192 in the counselor group
 - 193 in the web-based group
- A sample of 225 participants in each arm would produce a power of $>99\%$ to detect a within-group reduction in FRS of 1.5 % points. This sample size would additionally provide 85% power to detect a 0.9 % point difference in FRS between groups.
- Data handling method was intent-to-treat

RESULTS

- 29 patients were lost to follow up
- **Primary outcome measure:** For FRS in the counselor group there was a -2.3% and -1.9% change at 4 and 12 months ($p < 0.001$), respectively. In the web group, it was -1.5% and -1.7% at 4 and 12 months ($p < 0.001$), respectively.
- **Secondary outcome measures:** Adjusted change (standard error) in FRS at 4 month follow up was -2.4 and -1.4% for counselor and web, respectively; for a difference of -1% (95% CI, -1.8 - -0.1%) ($p = 0.03$). At 12 month follow-up, the adjusted change in FRS was -2.1 and -1.5 for counselor and web, respectively (95% CI, -1.7 to 0.5%) ($p = 0.3$).
- **Author's conclusion:** The combined L&M intervention tested in alternative formats yielded a substantial and sustained reduction in predicted 10-year CHD risk. Risk reduction was similar in both formats but web-based was less expensive to implement. Future research should assess implementation and maintenance of high quality evidence-based interventions in a broad selection of clinical settings. Also, the lifestyle component of these interventions should be studied in non-clinical health promotion settings

STRENGTHS

- Standardized format for both groups
- Random assignment for each group
- Inclusion and exclusion criteria allowed for extrapolation to the population of interest
- Study design allowed analysis of how different individual factors contributed to the results

LIMITATIONS

- Short study duration
- Unblinded
- Sample size was not sufficient to achieve goal power
- Some data was self-reported
- No (non-intervention) control group

CONCLUSION

- The study did not evaluate a large enough sample of patients to gain the results they desired therefore effectiveness of the lifestyle and medication intervention study cannot be determined and the null hypothesis cannot be rejected
 - patients were allowed to choose as many interventions as they wanted, an analysis should have been conducted on whether the number of interventions has an affect on the results
 - Cost-effectiveness used an average income from BLS that was higher than a majority of the patients in the study
 - Clinically, the use of intervention programs is an important part of managing patients' medical conditions and further studies should be done with a larger sample size to determine the effectiveness of these intervention programs, so that they may be improved
 - Since the baseline FRS was between 16 and 17% the decrease acquired from the interventions in this study did not lower them enough to decrease their risk very much
- Future research:
 - Consider patient access to internet and better evaluation of computer usability
 - Study a larger sample of patients from more diverse locations
 - Obtain a better estimate of patient income to assess cost
 - Use a no intervention control group

Reference: Keyserling T, Sheridan S, Draeger L, Finkelstein E, Gizlice Z, Kruger E, et al. A Comparison of Live Counseling With a Web-Based Lifestyle and Medication Intervention to Reduce Coronary Heart Disease Risk: A Randomized Clinical Trial. JAMA Intern Med. 2014 [Epub ahead of print]

Kayla Mitchell, Doctor of Pharmacy Candidate