

Study Protocol

“Main and Interactive Effects of Diabetes Distress and Stress from Life Events on Overall Psychological Distress”

The data for the study reported in the manuscript are from a larger study on psychosocial factors related to diabetes management (“The Diabetes Experiences Study”). The study received initial IRB approval from Rutgers University in March 2013 and renewed every year since. The total number of participants included 119 middle-aged and older adults with type 2 diabetes residing in the greater Philadelphia area. Recruitment fliers were posted in local places of businesses that allowed for advertisements (e.g. grocery stores, pharmacies) and healthcare provider offices (e.g. primary care physicians, diabetes educators). Advertisements for interested participants also were placed in local periodicals and websites (e.g. Craigslist). Additionally, research assistants attended various local community events (e.g. Collingswood Market, Step Out for Diabetes event) to spread the word about the study and distribute fliers.

All interested potential participants were screened for eligibility with an eligibility screening questionnaire. Eligibility criteria consisted of being between the ages of 45-85 years old; diagnosed with type 2 diabetes; seeing a healthcare provider to manage diabetes at least one per year; being fluent in the English language; and being free of significant cognitive impairment. Eligible participants who agreed to participate were given consent forms and information about how to complete the study. Before the interview, participants were asked to complete a self-administered questionnaire either over the phone, through email, or via mail. If participants were unable or unwilling to complete the form prior to the interview, this portion was completed at the scheduled appointment time. Participants were given the option to email, mail, or bring the pre-interview questionnaire with them to their scheduled appointment. Participants typically completed the questionnaires through an in-person interview, either at the Relationships, Health and Aging lab on the Rutgers Camden campus or at another convenient location (e.g. a participant’s home, local library).

The procedure and consent forms were briefly reviewed again at the beginning of the interview, and participants were asked if they had any questions before proceeding. Participants then began a structured interview with trained undergraduate and graduate research assistants, which lasted approximately 90 minutes (but ranged between one hour to two hours across participants). Interviewers read each question aloud. At the beginning of the interview, a standardized cognitive screening scale (Pfeiffer, 1975) was administered to assess any major cognitive impairments. (As a result of the assessment, no participants were judged to be cognitively impaired.) To aid in comprehension, cards with each response option were provided for all multi-item response scales, so participants had a visual reference for their answers. Participants were offered breaks between each interview section and were offered another opportunity to ask questions at the end of the interview. After the interview, participants completed a post-interview self-administered questionnaire. A brief exit survey also asked participants about any questions or concerns they had related to their participation. A list of local diabetes and mental health resources were given to participants. All participants were compensated \$20 in cash for their time, and received a reusable grocery bag with the study logo. Participants also were entered into a raffle for a chance to win an additional \$100. Finally, participants traveling to the Rutgers-Camden campus were compensated for parking and bridge toll costs.

For participants who were interested in the study, but could not commit to an in-person interview, a mail-out version of the interview materials were made available, which included return postage. Participants who chose to complete the mail-out version of the questionnaire were given contact information for the lab if they had any questions regarding the materials and were allotted at least 2 weeks to complete the materials (of which, participants typically spent between 60-90 minutes completing the questionnaires). Participants who opted for the mail-out version were compensated \$20 for their time, which was sent via money order after the completed questionnaire was returned to the lab. A variable for interview vs. mail version was developed to examine any significant differences in key variables by mode of survey administration. No significant differences were found in any key variables as a result of mode of administration.

References

Pfeiffer, E. A. (1975). Short Portable Mental Status Questionnaire for the assessment of organic brain deficit in elderly patients. *Journal of the American Geriatrics Society*, 23, 433–441.