Study Protocol
Official Title: Telemedicine for Reach, Education, Access, and Treatment-Ongoing (Treat-On) Study
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This was a 12-month non-randomized trial that evaluated TREAT-ON prospectively and compared it to a retrospective in-person diabetes self-management education and support (DSMES) program. Both programs were offered at Federally Qualified Health Centers (FQHCs) providing care to mostly medically underserved, underinsured and uninsured in rural communities located across three of the most distressed counties in Western Pennsylvania. The University of Pittsburgh Medical Center (UPMC) services extend across the region, and based on UPMC Health Plan data, approximately 1,300 adult patient-members with T2DM received care at the participating FQHCs (58% female, mean age 58y, >75% Medicare/Medicaid) at the time of the study. The FQHCs were chosen because they offered the UPMC Health Plan's *Diabetes High Risk Initiative*, an insurer-based DSMES program, to patient-members with a diagnosis of T2DM and considered to be at "high risk" for diabetes-related problems (Zupa et al, 2019). The purpose of this study was to compare TREAT-ON, an enhanced telehealth version of the *Diabetes High Risk Initiative,* to matched controls who had already completed the *Diabetes High Risk Initiative* in person. This study was approved by the University of Pittsburgh's Institutional Review Board.

Models for DSMES

The original Diabetes High Risk Program: The Diabetes Care and Education Specialist (DCES)-driven *Diabetes High Risk Initiative* (Zupa et al, 2019) was designed to address key components that have been shown to improve quality outcomes in primary care that include, population health, self-management, and coordinated team care (Wagner et al, 1996). A DCES proactively identified high risk patient members and provided in-person DSMES. Patients were identified through the insurer's population health reports, which are routinely generated and reviewed to allow for proactive identification of individuals who may benefit from supplemented chronic care management. The DCES created a referral for DSMES to patients considered to be at high risk for diabetes-related problems who met the following criteria: diabetes-related emergency room visit or hospitalization, HbA1c >9%, and reported barriers to care. Barriers to care included lack of access to care because of transportation problems, cost barriers due to difficulty in affording medications and supplies, and challenges with comprehension of a care plan due to deficits in knowledge about diabetes or general health literacy. Treatment ranged from chart review and plan of care with medication recommendations to the primary care provider (PCP) to telephone-based or in-person individualized DSMES sessions with patients, depending on patient needs and preferences. The DSMES sessions were in keeping with the assessment and content presented in the National Standards for DSMES (Davis et al, 2022).

The TREAT-ON Model: TREAT-ON (Figure) is an enhancement of the *Diabetes High Risk Initiative* with the addition of real-time telemedicine videoconferencing to allow remote access to self-management support within the privacy of a patient's home (or location of their choosing). Recognizing that rural communities experience challenges with internet connectivity that could preclude participation, we learned that 96.5% of the population in the area, where the study was conducted, was reported to have broadband connectivity.

The DSMES intervention was initiated by the DCES where a comprehensive assessment (review of clinical needs, history, psychosocial needs and barriers, current therapy, nutrition, activity, risk factors, coping strategies, problem solving skills, with attention to health literacy and cultural influences) was conducted. Based on the assessment, the DCES collaborated with the patient (and PCP) to establish an individualized treatment plan with medication recommendations and self-management goal(s), as well as provide DSMES. Building on this, ongoing management and support was delivered to the patient (and their caregiver if invited) via

videoconferencing. As part of ongoing support, the DCES was available upon need and request to the patient over the 12-month period, the DCES had the opportunity to assess an individual's progress towards meeting their self-management goals, address challenges and barriers that may be impeding progress, and reinforce self-care behaviors, problem solving-skills and coping strategies. Consistent with the patient empowerment–oriented approach, a patient-centered model tailored to meet the patient's needs (Anderson et al, 1995) the DCES collaborated with the patient to determine content for discussion, number, length and frequency of follow-up sessions. Content was in keeping with the National Standards for DSMES (Davis et al, 2022).

Recruitment, Enrollment and Training

Study patient participants were identified through the UPMC Health Plan population health reports and were invited to participate by a DCES at a participating FQHC if the individual met the "high risk" conditions (Zupa et al, 2019). Participating patients were consented and introduced to the TREAT-ON model and familiarized with the telemedicine videoconferencing technology by the DCES and health system's technology staff.

Outcome Measures

Data were collected at baseline and 3, 6 and 12 months for all outcome measures except for intervention acceptability, which was only assessed at follow-up. HbA1c served as the primary outcome and clinical measure of improved DM management. HbA1c values were obtained from the patient's medical record. Behavioral and psychosocial outcomes were assessed with validated self-report instruments.

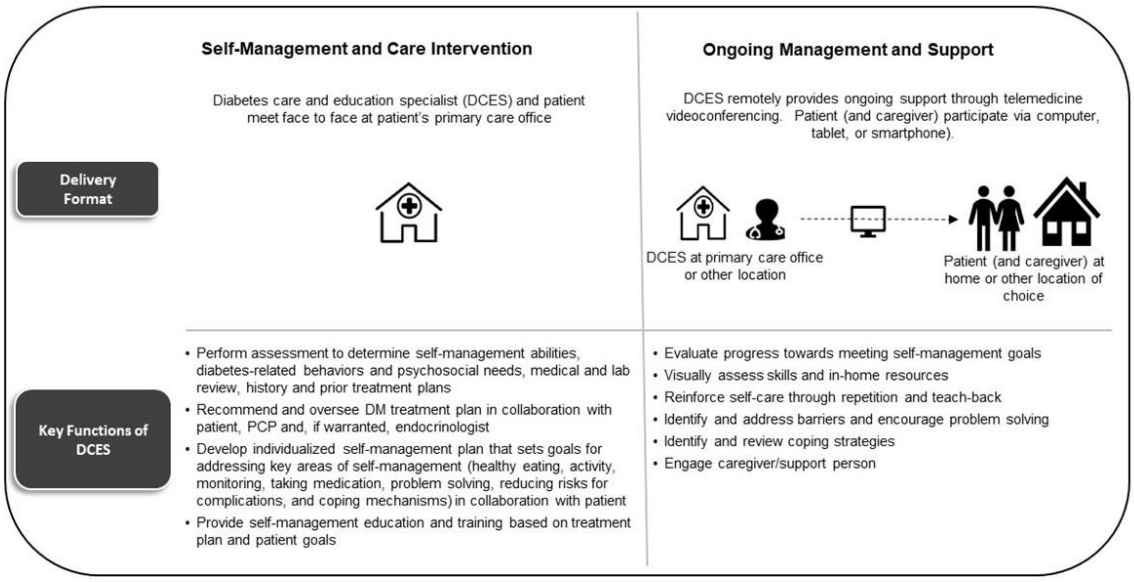

Figure. Overview of TREAT-ON Model of Care

References

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