Virtual Coaching to Maximize Dementia Caregiver's Respite Time Use

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Time for Living and Caring (*TLC*) Study:
A Research Study to Learn How Dementia Caregivers Use Respite

This research is funded by a grant from The National Institute on Aging.

You are invited to take part in the *Time for Living & Caring* (*TLC*) research study because you are the caregiver to someone with Alzheimer's Disease or dementia, and because you are using or have a desire to use formal respite services (such as home-care respite providers or adult daycare providers) or respite provided to you by your family members or friends.

Respite is defined as an intentional, temporary break from your caregiving responsibilities. When used consistently, respite has been associated with improved health and well-being for caregivers. All caregivers need respite. All caregivers deserve respite. But not all caregivers use respite as effectively as they could.

The purpose of the *TLC* study is to find out if 1) using an online calendar and goal-setting and goal-review exercises can help improve a caregiver's use of respite, and 2) whether better respite time-use is associated with more favorable health and well-being over time.

Participation in the *TLC* study is voluntary. Participants will complete 6 questionnaires and use the *TLC* online/web-based tools at least weekly over a 5-month (20-week) time period. Participants will receive compensation (up to $250) for participating in the *TLC* study.

This document outlines your rights and responsibilities as a participant in the TLC study. Please review this document carefully, keep it for your records, and ask any additional questions to the TLC research staff if there is anything you do not understand.

TLC
TIME FOR LIVING & CARING

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BACKGROUND AND PURPOSE of *TLC* STUDY

Respite is defined as time-away from caregiving duties and activities. It can be provided formally by home health aides or respite providers who come into the home to take care of your loved one while you take a break for yourself, or informally by family members, neighbors, and friends stepping in to give you an occasional break.

Respite has been identified as the most needed and desired service for family caregivers, especially the 16 million dementia caregivers who are faced with long term and demanding caregiving circumstances.

Research has found that when caregivers use respite consistently and plan what they want to do during respite, they have favorable outcomes such as reduced caregiver-related stress and better overall health and wellness.

Researchers at the University of Utah developed a support program called "Time for Living & Caring" (*TLC*) that has been used to successfully help caregivers improve their respite time-use. The *TLC* program uses a calendar, along with basic goal-setting and goal-review strategies, to help caregivers schedule, plan, and review their respite time-use and respite needs. The original *TLC* program used trained facilitators to go to the caregiver's home or to have consultations via telephone, up to 15-20 times. That was an unrealistic way to provide support to caregivers.

The purpose of this study is to redevelop the *TLC* program to a fully online, self-administered format, and then to pilot-test the new online version of the *TLC* intervention for feasibility and efficacy. *Do caregivers like to use and/or benefit from the online version of the TLC tools? Do these tools improve caregivers use of respite, and enhance their overall health and well-being?*

STUDY PROCEDURES

As a participant in the *TLC* study, you will first receive a phone call from a member of the *TLC* research team, who will make sure that you meet the criteria for being in the study and that you are willing to participate. You will need to have access to the internet and a computer to participate in the study. If you do not have access to these technologies, we can provide you with a netbook and access to high-speed internet for the time of the study.

After consenting to participate, you will be randomly assigned to either group #1 or group #2. The decision of which group you will be assigned to will be chosen by chance, like flipping a coin. You will have an equal chance (50:50) of being in group #1 or group #2.

Participants in both groups will have access to the *TLC* online tools for 16 weeks. All participants are expected to log-on to the *TLC* website at least weekly and to spend a

minimum of 5-10 minutes per week planning and reviewing their respite time-use. The *TLC* website contains a calendar to schedule respite time, as well as goal-setting and goal-review features that help caregivers plan and review how they want to spend their respite.

The only difference between group #1 and group #2 is in how the instructions and features of the *TLC* program will be delivered:

> Those in group #1 will receive instructions and full access to the features of the *TLC* program beginning week 1. They will practice using the *TLC* calendar + the goal-setting and goal-review functions for the entire 16-week period.
>
> Those in group #2 will receive instructions and access to the calendar features of the *TLC* program on day 1, allowing them to schedule their respite time for 8 weeks and hopefully gain a more consistent respite schedule. Then, at week 9, they will be given access to the goal-setting and goal-review functions.

The goals for group #1 and group #2 are the same: 1) to achieve a more consistent respite schedule and 2) to improve the quality of respite activities over time. Comparison of these two groups tell the researchers which type of delivery and instructions are most useful to caregivers. We have reason to believe that both approaches are valid and will lead to positive results and behavior-change among participants.

All participants, whether in group #1 or group #2, will be asked to complete a series of six electronically-delivered surveys, delivered through email every four weeks. The first survey will be the longest, taking approximately 30-45 minutes to complete. It will be delivered immediately upon enrollment into the study. Additional surveys will be completed every four weeks, with the final survey delivered at week 20, one-month after the end of the 16-week *TLC* program. The monthly follow-up surveys will be shorter than the initial survey, taking approximately 5-25 minutes to complete. Questionnaires will include mostly fixed-choice survey questions that help the researchers understand who you are, what you do as a caregiver, how you are using or want to use respite, and also how you are feeling about your caregiving role over time. The final questionnaires will also ask participants about their use of the *TLC* online tools and how they think the tools might be further refined in the future.

Should there be any unanticipated problems or barriers to using the online tools, all participants will have access to members of the *TLC* research team and the *TLC* live coach throughout the 20-week study period. The *TLC* online program also includes resource pages to help foster success and to provide referrals and general information useful to family caregivers.

Participating in the *TLC* research study will last 20 weeks.

NUMBER OF PARTICIPANTS

We expect to enroll approximately 150 participants in the *TLC* research study.

RISKS

The risks associated with participation are minimal. You could become fatigued completing surveys or online activities. Some of the questions on the surveys could potentially cause an upsetting emotional response like sadness or crying if you are describing negative aspects of your caregiving experience. If that happens, you can leave the question unanswered or come back to the question at another time when you are not upset. You do not have to answer any questions that you do not want to answer. You may stop answering questions at any time.

BENEFITS

We cannot promise any benefits from taking part in this research study. However, the knowledge the researchers gain about caregivers' use of respite has the potential to improve respite services, by allowing us to learn the most effective and preferred ways caregivers use and plan their respite, and whether the *TLC* tools are useful in maximizing the benefit of respite. Individual caregivers may potentially discover ways to make more effective and beneficial use of respite, which may have positive effects on their overall health and well-being over time.

COSTS AND COMPENSATION

There will be no cost to you to participate in the *TLC* research study.

In recognition of your time, you will receive an incentive (in the form of gift cards and/or a new netbook) equal in value to $250. Payment for partial participation will be prorated accordingly. If you choose a netbook as your form of compensation, and you do not finish the study, you will be asked to return the netbook.

Depending on the amount and method of compensation you receive, you may be asked to give us your social security number. You will give us this information on a W-9 Form that will be filed with the University of Utah Accounts Payable department. You can still participate in the study and not give us your social security number. However, we may not be able to pay you as outlined in this consent form.

VOLUNTARY PARTICIPATION & ALTERNATIVE PROCEDURES

Participation in the *TLC* research study is voluntary. You have the option to not be part of this study. If you do not take part, you can continue to provide care and to use respite the way you are using it now. Your decision to participate will not result in any penalty or loss of benefits to which you are entitled. Your decision to participate will not affect your legal rights or access to any existing respite services you are using.

CONFIDENTIALITY

The *TLC* research team will do everything we can to keep your information private, but we cannot guarantee this.

- We may need to disclose information revealed to us, if required by law.
- We will enter the information you provide for this research study into a secure electronic database. All electronic records will be password protected, and only accessible to trained *TLC* research staff. We will use your information for statistical analysis, which may appear in scientific publications, but the information stored and analyzed will not include your name, address, social security number, date of birth, or any other personal identifiers. Instead, we will use a unique code for each person consisting of a number and the first letter of your first name. The researchers will keep the key linking your information and your identity in a locked file. Only the *TLC* research staff will have access to the key, and will only use identifying information in the event they need to contact you regarding your participation in the study.
- If we lose track of you, *TLC* research staff may collect information from the internet including social networking sites in order to find your contact information.
- *TLC* research records and results from the *TLC* study may be used and reviewed by others, such as:
    - The University of Utah Institutional Review Board (IRB), which reviews research involving human subjects to make sure your rights as a research participant are protected
    - The National Institutes of Aging, the sponsor of this study, including persons or organizations working with the sponsor
    - Other researcher investigators. In this case, the dataset shared with them will not contain any identifying information about participants.

RIGHT OF INVESTIGATOR TO WITHDRAW

We expect to continue the *TLC* study until all participants have been enrolled and all of their information has been collected. However, the study may be stopped at any time by the researchers or by the National Institute on Aging. The researcher may also withdraw you from the study without your approval. One reason this may happen is because the researcher feels it is necessary for your health and safety. Another reason is if the entire study is stopped.

NEW INFORMATION

During the course of the study, we may find new information that could be important to you. This includes information that may cause you to change your mind about being part of the study. We will notify you if any significant new information becomes available which may affect your health, safety, or willingness to continue in this study.

CONTACT INFORMATION

If you have questions, complaints or concerns about this study, you can contact the *TLC* study coordinator at 801-213-1530 or *TLC*@utah.edu or the principal investigator Dr. Rebecca Utz at 801-581-7922 or rebecca.utz@utah.edu.

If you think you may have been injured or harmed from being in this study, you can contact the Institutional Review Board (IRB) at the University of Utah. You can also contact the IRB if you have questions regarding your rights as a research participant or if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached at (801) 581-3655 or irb@hsc.utah.edu.

You may also contact the Research Participant Advocate (RPA) at (801) 581-3803 or participant.advocate@hsc.utah.edu.

By completing the study procedures, you give your consent to participate in the *TLC* study.

As the study is completed, research findings will be posted on the *TLC* study website.

https://www.tlc.gslc.utah.edu