

THE EFFECT OF OPEN-LABEL PLACEBOS ON NONMARITAL ROMANTIC BREAKUP  
RECOVERY: A STAGE 1 REGISTERED REPORT STUDY

By

GABRIELLE RICE

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A Thesis Submitted to The Honors College  
In Partial Fulfillment of the Bachelors Degree  
With Honors in  
Psychology  
THE UNIVERSITY OF ARIZONA

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Approved by:

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Dr. David Sbarra

Department of Psychology

A Registered Report is a new style of scientific research paper that is gaining increasing prevalence in the literature (Chambers & Tzavella, 2022). Registered Reports involve the submission of a Stage 1 paper for peer review prior to data collection, or in the case of an ongoing data collection/secondary data analysis, prior to evaluating the aims of the study. Stage 1 manuscript submissions are written in the past tense, as if the study was completed (through the end of the Results); all expected findings are denoted with **XXX and highlighted in YELLOW**. My honors thesis is written in the style of a Stage 1 manuscript for the Open Label Placebo Study. My role on the OLP study to date: Assisting study conceptualization and Human Subjects ethics approval; study management and data collection.

## Abstract

Nonmarital romantic breakups are difficult and emotionally painful experiences. Recovery can take from weeks to months, and there are very few established interventions that exist for helping to promote recovery. Recent research reveals that open-label placebos (OLPs), which are placebos prescribed to a patient who knows the medication is inert and functions via the placebo effect, have proven effective in reducing subjective experiences of pain in chronic medical conditions. This study has borrowed from literature about OLPs in order to conduct a pilot study examining whether there is initial efficacy for an open-label placebo in promoting breakup recovery. Specifically, XXX college-aged young adults who had recently experienced a stressful romantic breakup were randomly assigned to either a control condition (measurement only) or an experimental condition in which they completed the study measures and received a Zeebo placebo pill every day for the duration of the five weeks of the experiment. In the experimental condition, participants were explicitly told that they were receiving an inert pill, but they were informed that placebo interventions show beneficial effects. We hypothesized that participants who received the open-label placebo would show an increased rate of recovery relative to those who did not receive the open-label placebo over the 5-week course of treatment and observation.

*Key words: open-label placebo, placebo, breakups, breakup recovery*

Romantic breakups are incredibly common, and most people will experience a nonmarital romantic breakup during their college years and beyond. In fact, in a study done by Susan Sprecher, she found that 59% of the couples in her study on college romantic relationships were broken up within 5 years (Sprecher, 1999). Breakups are incredibly mentally taxing in a way that is measurable beyond personal anecdotes. They are known to predict heightened anxiety, increased depression, as well as feelings of loneliness, rejection, and betrayal (Field, 2017). In fact, a study by Field (2017) reveals how a breakup can lead to chest pain and compromised immune function; specifically, this author notes that breakups have been associated with increased stress hormones and disrupted sleep function which may lead to immune depression on top of emotional symptoms. The immune depression is likely associated, Field explains, with increased heart rate, blood pressure, cortisol, and norepinephrine levels following heartbreak, as discovered in a range of studies. She further notes that sleep disturbances can range from increased REM density to insomnia (Field, 2017). Fortunately, studies show that most young adults, drawn from a pool of college students, can cope effectively with breakups and prove to be resilient with a proper support system (Sprecher, 1999). In essence, most college students going through a nonmarital romantic breakup will make full recoveries without the help of any kind of intervention. Even still, there is very little research into how one might expedite the emotional healing from a nonmarital romantic breakup.

While there has been little research into breakup interventions, there have been other studies which focused on the factors that shape the course of breakup adjustment. One study, for example, focused on forgiveness of an ex-partner. This study implemented a number of self-report measures that focused on examining measures like the level of romantic attachment to the former partner as well as evaluating forgiveness and the adjustment to the divorce or separation.

The results in this trial showed several things; among them, it showed that attachment anxiety was associated negatively with forgiveness of the former partner, and enhanced loneliness as well as attachment to the former partner. Meanwhile, attachment avoidance was associated with higher loneliness and attachment to the former partner, but was not linked to forgiveness.

Overall, the study found that forgiveness of the former partner was associated with a decrease in both loneliness and attachment to the former partner (Guzmán-González et al., 2019).

Additionally, research has been done into the tendency of people dealing with a recent breakup to desire attachment or avoid attachment with their former partner using an Approach Avoidance Task (Eisma et al., 2022). This study in particular relied on two measures of attachment style; they analyzed attachment anxiety (that is, how one experiences their typical close relationships) and desired attachment (as in how much they still desire to use their ex-partner as an attachment figure). Another study examined the college-aged romantic breakup by evaluating how a person copes with their breakup while considering what the study refers to as their *time perspective* (how a person uses their chronological classification to make sense of their experiences) and their parental bonding. The results showed that participants with secure parental bonding and with a positive time orientation were less distressed following a breakup, whereas participants who exhibited a higher future relationship orientation reported heightened levels of distress. (Gilbert & Sifers, 2011).

Although the research described above is undoubtedly valuable, none of these studies offer any intervention for the distress relating to a breakup. There has been some minor research into possible interventions, including a study that examined whether or not there would be a difference in the rate of recovery between research participants who participated in studies of their coping versus subjects who did not. In the study, 210 participants who had recently

experienced a nonmarital romantic breakup were divided randomly into a measurement-intensive condition or to a pre-post condition. Participants in the measurement-intensive condition participated in a number of self-report measures over the course of four visits with researchers. In contrast, participants in the pre-post condition were only assigned to participate in the first session and the final session in order to gauge their recovery without the intervention of self-report measures. The study found that participants who participated in the intervention (that is, the measurement-intensive condition) showed less self-concept disturbance than did the control group (Larson & Sbarra, 2015).

Given that (a) relationship breakups place people at risk for emotional distress and even clinically-significant mental health disorders, and (b) few interventions exist to promote breakup adaptation, my honors thesis approaches the question of improving the course of adjustment (to a breakup) in a new and innovative way. In particular, this work introduces a small-scale intervention using an open-label placebo (OLP) method to determine if simply asking people to take a placebo pill, once a day for a month, can help initiate positive changes and promote recovery.

### **Placebos and Recovery**

The placebo effect occurs when a patient is given a treatment—usually in the form of a sugar pill—that is completely inert (i.e., no biological impact on a person) and show improvement in the outcomes of interest. Placebos work by setting expectations in a patient's mind that this treatment will make their symptoms better, and it has been shown to be quite effective (Moseley et al., 2002). For example, a study in Houston, Texas in 2002 saw patients undergo a placebo knee surgery, having been randomly assigned to one of three surgical options: debridement, arthroscopic lavage, or a simulated placebo arthroscopic surgery. Participants were

not informed which surgery they received—though were informed that there was a one in three chance of receiving the placebo surgery—and subsequently had their recovery and pain levels tracked for a period of two years. During this time, it was observed that participants who received the placebo surgery experienced pain relief and better function in a manner comparable to the patients who had received real surgical intervention (Moseley et al., 2002).

In contrast to the standard placebo response derived in randomized controlled trials for medical interventions, an OLP effect occurs in placebo treatment wherein the patient is made *completely aware* that the treatment is an inert placebo but are also primed with the knowledge that placebo effects are beneficial for many people in many different situations. Although OLP research is in its infancy, the evidence to date on their efficacy is promising. For example, in a treatment study of Irritable Bowel Syndrome (or IBS; Kaptchuk & Miller, 2018), patients with IBS were recruited to try what was explained to them as a “novel mind-body management study of IBS.” Prior to the randomization of subjects, they were informed that they would either be assigned to a placebo condition or to a no-treatment condition. Once selected, participants were given even more information about open-label placebos and how they would be beneficial due to the power of placebos; moreover, they were informed that their bodies would eventually respond to the placebos as if it were conditioned, regardless of whether the participant had a positive outlook (although a positive attitude is helpful). Participants in the OLP condition were advised that taking the pills faithfully was critical to the impact of the treatment; participants were to take two placebo pills twice daily during the three-week course of the study. It was discovered that patients who took the OLP had significantly improved scores on the Global Improvement Scale at both the 11-day midpoint as well as the 21-day endpoint of the experiment (Kaptchuk & Miller, 2018).

Another study focused on whether or not OLP could be effective for managing fatigue in cancer patients. Like the study on IBS, participants were primed with knowledge about OLPs and then divided into two groups referred to as the OLP group and the TAU group (for Treatment As Usual). Participants in the OLP condition were instructed to take two placebos twice a day. Interestingly, participants in the TAU group were advised that, at the end of the 21 days of the study, they were also going to have the OLP made available to them. The results of this study were much the same as the IBS study, wherein the OLP condition proved more effective than TAU. This result was only further reinforced when TAU participants elected to take the OLP (Hoenemeyer et al., 2018).

Other studies have even begun to reinforce the concept that an OLP may be useful in the treatment of emotional distress. In fact, one study done in Israel compared the effects of an open-label placebo on unipolar depression in comparison to treatment as usual. The study followed 38 patients diagnosed with unipolar depression for a period of eight weeks. Participants were randomly assigned to one of two conditions: OLP or another TAU (Treatment As Usual) condition. All participants were encouraged to continue any other therapy or treatment they were on, provided they were on a stable dosage for at least two weeks prior to their entry into the study. All participants were likewise informed about the potential they would be placed on a placebo pill, as well as the potential benefit of that placebo. Participants assigned to the OLP condition were instructed to take two placebos in the morning, and two again at night. Meanwhile, participants in the TAU condition were to continue all treatment as usual for the first four weeks. However, at the end of the fourth week, following a follow-up visit with the researchers, participants in the TAU group were also instructed to switch to the OLP treatment for the remaining four weeks. Participants in the OLP condition have no change, and continue



the OLP. The results showed that both groups showed a drop in their rates of depression, which suggests that OLP may be a beneficial additional treatment for patients with unipolar depression. This suggests that open-label placebos are not only potential forms of treatment, but also that they might be effective in treating emotional symptoms as well as physical symptoms (Nitzan et al., 2020). Another pilot study examined the use of OLPs in the treatment of major depressive disorder (MDD). All participants were primed with information about placebos and why OLPs specifically might be effective in treating their depression. The study randomly assigned participants who had non-psychotic MDD into one of two categories: OLP or waitlist. For the first two weeks of the study, participants in the OLP group were assigned to take two OLP pills (blue capsules containing microcrystalline cellulose) twice daily, while waitlist participants waited. Following the first two weeks, participants in the OLP condition were given an additional four weeks on the placebo. Meanwhile, the waitlisted participants were then assigned to participate in the OLP regimen for the remaining four weeks of experimentation. Blinded clinicians then assessed the participants at baseline and every two weeks thereafter using a variety of self-report questionnaires (including the 17-item Hamilton Scale for Depression, the Quick Inventory of Depressive Symptoms, and the Symptoms of Depression Questionnaire). The results showed that there were statistically significant pre-post improvements on all three outcome measures after four weeks of OLP treatment with moderate to large effect sizes (Kelley et al., 2012).

### **OLPs and Breakup Recovery: Why and How?**

One of the primary differences between an OLP and a regular placebo is also the style of experiment; with a placebo trial, the patient is told that it is possible for them to receive the treatment or the placebo. An OLP trial, however, assigns people to the placebo as the form of

treatment and makes it known that placebos can promote recovery, especially in situations where mind-body associations (e.g., in IBS) play a prominent role. In the context of a romantic breakup, why and how might the OLP be beneficial? There are a handful of reasons to expect that people experiencing a romantic breakup will improve as a function of taking an OLP. OLPs are already shown to work on depression and symptoms associated with depression, which indicates that there is potential for alleviating the emotional pain and depression that comes with a breakup. Moreover, OLPs have shown a wide range of other uses, which implies that it could also be beneficial for other emotional states as well as a wide range of physical states. There had not been much research into the efficacy of open-label placebos for helping people cope with stressful life circumstances. Open-label placebos have been primarily tested in the arena of physical ailment or pain, whereas the potential implications for emotional recovery have gone mostly unstudied.

### **The Present Study**

Using a sample of people who have recently experienced a nonmarital romantic breakup, this present study examined how an open-label placebo might impact the rate of romantic breakup recovery. Following prior research in this area (Larson & Sbarra, 2015), we defined romantic breakup recovery using three outcome measures: level of loneliness, level of event-based distress, and security in sense of self. Participants were randomly assigned to one of two conditions, experimental and control. During the duration of the experiment, both groups completed a series of pre-established self-evaluation measures in order to chart their general rate of recovery over the course of five weeks. Both groups participated in these self-evaluation measures in order to ensure that any and all measured benefits could not be attributed simply to the taking of these measures (Longwell & Truax, 2005). These surveys were delivered by Zoom

once a week for every week of the experiment. Participants assigned to the experimental condition additionally received information about open-label placebos and the likelihood that they would promote further recovery. From this point, experimental participants were given placebo pills and were instructed to take one pill by mouth every day. In this study, we hypothesized that our participants who received the open-label placebo would show an increased rate of nonmarital romantic breakup recovery relative to those who did not over the 5-week course of treatment and observation. I expected that participants in the experimental condition would see an increase in romantic breakup recovery, evidenced by a lowered impact of event, a lessening in levels of loneliness, as well as promoting greater security in their sense of self.

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## **Methods**

### *Participants*

Participants were **XXX** young adults (**XXX** men; mean age = **XXX** years, SD = **XXX** years, range = **XXX**) who had experienced a nonmarital romantic breakup within the past 6

months (average relationship length prior to the separation = XXX months, SD = XXX months; average time since separation = XXX months, SD = XXX months). The recruitment for this study was open, meaning that both same sex and heterosexual couples were able to participate. Participants were racially divided into XXX%. We did not collect information about participants' socioeconomic status. For the purposes of this study, participants were recruited based on their reactions to a recent breakup. They were recruited via emails as well as through the SONA system. Participants were asked how recently their breakup occurred, as .

Following their initial interest, potential participants were contacted via research assistants. From there, the participants were randomly assigned to either a control or experimental group. University of Arizona students who are enrolled in psychology courses were granted credit for their participation via the SONA system.

### *Procedure*

This honors thesis was most keenly interested in developing a possible intervention for nonmarital romantic breakup recovery. In this vein, participants who expressed interest were contacted by the study's research assistants. In order to begin enrollment, the participants are first randomized using a randomization table into either the control or experimental group. Once assigned, the participants were guided to the associated consent form to be signed. At this time, participants also fill out demographic information (ethnicity, gender, age, etc.) and make an appointment for a first visit with the researcher.

During their first visit, control group participants completed a series of baseline self-report measures which evaluated the impact of their breakup and experiences of breakup-specific distress, including a recorded 4-minute stream of consciousness (SOC) speaking exercise

probing their thoughts and feelings regarding their breakup. These self-report measures will be discussed in more detail below. Broadly, however, the measures will focus on the impact of the breakup and the emotional aftermath.

These participants would then make four repeat follow-up visits during which they will repeat these self-report measures as well as their SOC task. In total, participants will take these self-report surveys five times including the baseline assessments. Participants in both the control and experimental groups took a survey during weekly visits throughout the five-week research period in order to measure their scores on the self-report measures over time. It is important for both the control and experimental groups to complete these surveys because, as has been shown in studies like those done by Longwell and Truax, there has been measurable improvement in the reduction of symptoms of depression and anxiety just by repeatedly administering self-reports (Longwell & Truax, 2005). Having both groups complete these self-reports helps to eliminate this as a possible extraneous variable.

The experimental group will receive the same baseline assessment and will also participate in the follow-up assessments. The difference exists within the first month of the 5 weeks. For the first 28 days, experimental participants will be taking a sugar pill by mouth every day.

### *Measures*

*MIP/SOC Appraisal Form.* This self-report measure identifies how emotionally stressful or taxing the SOC task was for the participant. In this measure, they answered a series of eight questions on a scale (e.g., “overall, how upsetting did you find this task” and “how much did you allow yourself to freely experience your emotions during the task”) that asked them to select how

much they identified with a certain statement, ranging from 0 (Not at all/none at all) to 7 (Extremely).

*Patient Health Questionnaire (PHQ-9)*. This depression scale questionnaire evaluates whether or not a given participant might be struggling with a series of nine health-related problems (including “trouble falling or staying asleep, or sleeping too much” and “poor appetite or overeating”). They rate the frequency

*Inventory of Complicated Grief (ICG)*. The ICG is a 15-item self-report measure which assesses how one has coped (or failed to cope) with grief about the end of their relationship. The measure asks them to rate how often in a month they agreed with or felt similarly to certain phrases (e.g., “I feel I cannot accept the relationship ending” or “ever since the relationship ended, I have lost the ability to care about other people or I feel distant from the people I care about”) on a 5-point scale ranging from “Never” to “Always.” In this case, “never” is taken to mean less than once monthly and “always” means more than once a day.

*Impact of Events Scale-Revised (IES-R)*. The IES-R is a 22-item self-report measure that assesses feelings of distress after a particular traumatic event. This is the second, more in-depth version of the IES scales. It asks 22 questions geared to determine factors of hyperarousal, avoidance, and intrusion on daily life. Participants would look at statements talking about possible trauma symptoms, and rate whether or not they relate personally on a scale from 0 to 4, with 0 being “not at all” and 4 being “extremely.” The hyperarousal measures include phrases like “I was jumpy and easily startled,” or “I had trouble concentrating.” Avoidance questions include “I stayed away from reminders of it,” or “I tried to remove it from my memory,” while intrusion is measured through statements such as “any reminder brought back feelings about it” or “other things kept making me think about it.”

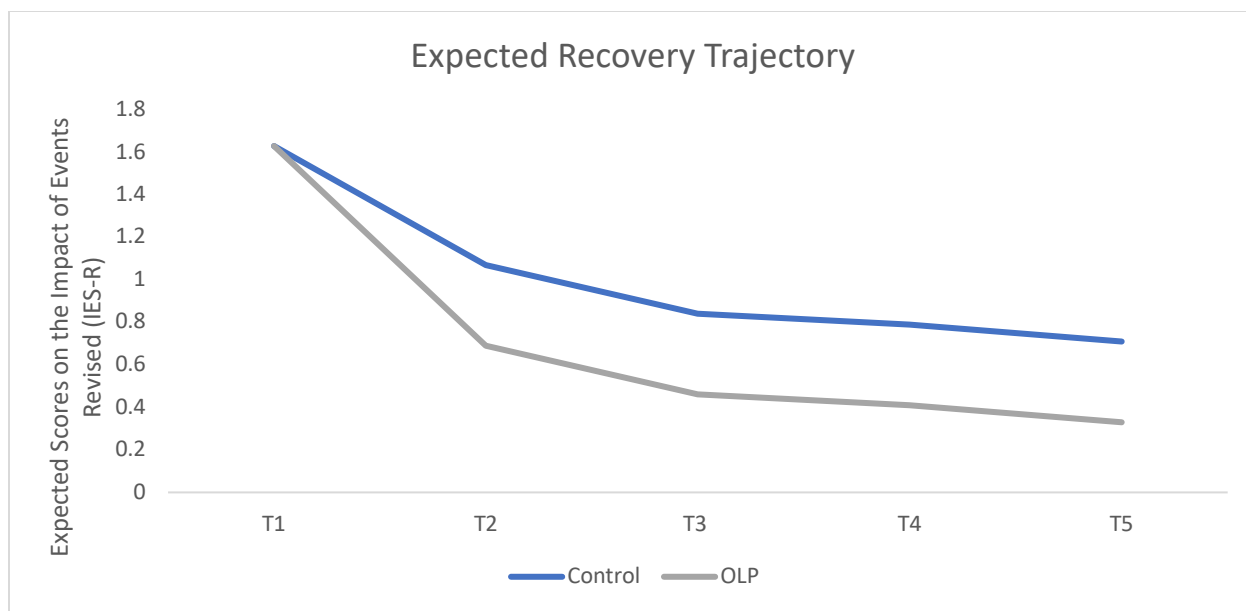
*Loss of Self and Rediscovery of Self (LOS/ROS)*. The Loss of Self Scale is a 6-item loss-of-self scale measured on a 7-point Likert scale ranging from 1 (*not at all*) and 7 (*a great deal*). Participants ranked statements like “I do not know who I am” and “I have lost my sense of self.”

*Revised UCLA Loneliness Scale (UCLA)*. This scale only has three questions: How often do you feel that you lack companionship? How often do you feel left out? And how often do you feel isolated from others? This scale uses three response categories on a 1-3 range, with 1 being “hardly ever,” 2 being “some of the time,” and 3 being “often.” Scores between 3 and 5 are ranked as “not lonely,” while 6 and above is considered “lonely.”

## **Expected Results**

The primary hypothesis of this study is that participants in the OLP condition, relative to those in the control condition, will show greater improvement in breakup-related psychological distress over time. I generated my expected results trajectory based on the pattern of findings observed in the Larson et al. (2015) paper. These findings, for the Impact of Events-Revised (IES-R), are displayed in Figure 1 for the control group.

Estimating the observed effect for participants in the OLP is somewhat tricky because we have no prior basis for this estimation in the breakup literature. Kelley et al. (2012) reported an average within-person effect size for participants in an OLP treatment of depression to be  $d = .58$ , and we used this effect size as the estimated rate of total change we would observe in our sample (see Fig 1).



## Discussion

Romantic breakups in young adulthood are highly stressful experiences and associated with a range of negative emotional outcomes (Field, 2017). For example, one study of university students divided up participants who had been through a breakup into high and low breakup distress conditions based on their scores on the Breakup Distress Scale. The higher breakup distress score participants had some common traits: 1) less time following the breakup; 2) assigned higher ratings to their former relationship; 3) had a longer relationship duration prior to the breakup. People in the higher distress rated group struggled with intrusive thoughts, had higher scores on the Difficulty Controlling Intrusive Thoughts Scale, had higher sleep disturbance scores, higher depression scores, and higher anxiety scores than did those in the low distress group (Field et al., 2009). Although breakups are associated with risk for poor outcomes, very few studies have sought to intervene or promote positive adaptation through experimental means. My honors thesis was designed to explore the impact of an open label placebo (OLP) as a novel means of promoting breakup recovery. As part of my thesis, I helped design, secure human



subject ethics approval for, and run a novel OLP study. Although the data collection on this study remains open, my thesis outlined a series of expected results, and I organized my work as a Stage 1 manuscript for a Registered Report (Chambers & Tzavella, 2022).

### **Why Study OLP in the Context of a Romantic Breakup?**

OLPs are known to have powerful effects on the human body, although the mechanisms explaining the benefit effects remain somewhat mysterious. Research has shown that being primed to think about one's recovery is effective, and the open-label placebo might create the expectation of expedited emotional healing. With these factors in mind, we suspected that the open-label placebo will have an impact on the rate of recovery in a manner similar to results shown for physical conditions. Placebos alone are capable of incredible things, from use in medical trials to a simulated placebo arthroscopic surgery (Moseley et al., 2002). With the wide application of typical placebos in mind, it would seem a natural step to test the limits of OLPs with the same dedication and optimism. OLPs have already proven themselves to be incredibly useful in the arena of physical symptoms in the treatment of IBS, which suggests that there is potential for curbing the physical side effects which can plague participants following a stressful breakup (Kaptchuk et al., 2010). Given the number of physical symptoms that have been observed in people following a heartbreak—heightened blood pressure, sleep disturbances, immune system deficiencies, etc.—there seems to be a great chance for OLPs to mitigate the damaging effects of these symptoms.

Moreover, OLPs have shown some use in the emotional arenas surrounding depression, as in the study by Nitzan et al., (2020). With this in mind, there is a great avenue of exploration to be considered. Breakups are known to cause feelings of depression and anxiety (Field et al., 2009), as well as feelings of betrayal and rejection (Field, 2017). Given the effectiveness

previously established by OLP trials, it was our hope and hypothesis that an OLP prescribed following a nonmarital breakup would allow for expedited healing as well as a freedom from painful emotional symptoms.

### **Research Process and Lessons Learned**

This Honors Thesis was a long but rewarding process. I was initially brought into the process of setting up the protocol of the study and mitigating (to the best of my ability) confounding variables. I was heavily involved in the initial proposal for the IRB, and in doing so developed a greater understanding of the IRB process overall. I learned how to format and how to use scientific language to its full potential. Primarily, I worked behind the scenes looking at incoming data and ensuring that each of the assigned questionnaires were filled out and implemented correctly in the systems used. I functioned as a coordinator and ensured that the audio files for stream-of-consciousness (SOC) tasks were placed in the correct location with the correct tags. This helped me to understand the complex nature of data storage during a study, as well as keeping up with the scheduled visits for participants in order to be sure that I knew what files were to be expected at what times.

This study enabled me to gain a broader understanding of the conducting of research, as well as to be rigorous in my approach towards moving forward in research. This study also helped us to understand why the open-label placebo effect might work here. One of the primary aspects of placebos overall are intention and expectation. Our study aimed to reinforce and expand upon this literature in order to better understand the root cause of the placebo effect overall—but more specifically, the effect of a non-deceptive placebo.

There were a few limitations to our study. Primarily, the additional wrench of COVID-19 might have made it difficult to find participants, but also carried with it potentially complicating variables. Baseline assessments were able to be accessed regardless of modality. Another potential limitation is that we will be focusing primarily on college-aged individuals, and thus cannot necessarily generalize to a larger segment of the public.

### **Conclusions and Future Directions**

Developing OLP interventions for romantic breakups, or any stressful situations for that matter, may be a promising scientific endeavor. Relative to a comparison condition of simply participating in a research study, which itself is modeled on an experimental methodology that promotes adaptation (Larson & Sbarra, 2015), we expect the OLP intervention to improve the course of a breakup recovery. Ultimately, our study aims to be one of the largest OLP investigations to date, which has the potential to help us determine if the observed effects are practically meaningful—does an OLP help people *feel better* about their breakup in a noticeable way? I look forward to following the progress of this study and assisting in the future where I can as data collection continues.

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