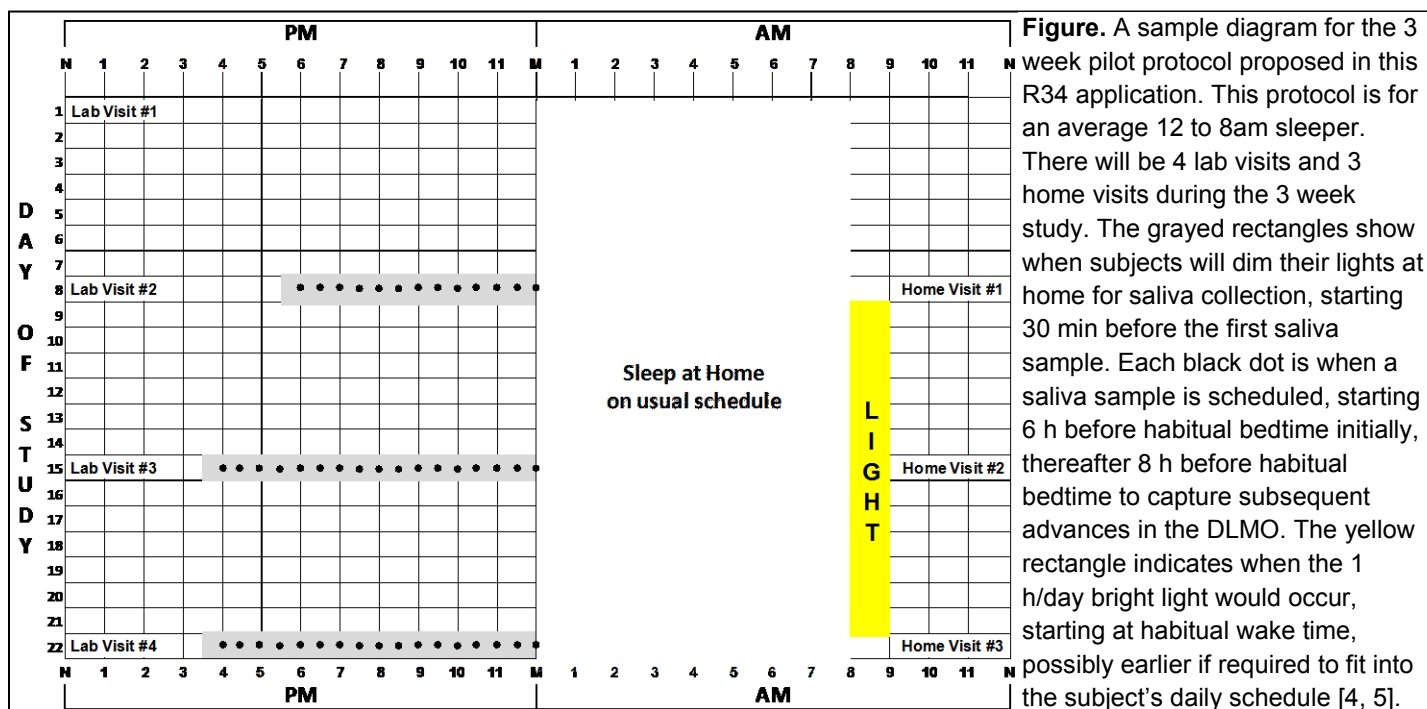


Bright Light Treatment At Home To Manage Chronic Pain In U.S. Veterans

NCT02373189

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## Protocol for ORA# 13082603: Bright Light Treatment at Home to Manage Chronic Pain in US Veterans



### Protocol

A sample protocol for this pilot study is shown in the Figure above. On Day 1 (lab visit #1) subjects will complete questionnaires, receive a wrist activity monitor, and a Personal Data Assistant (PDA; electronic diary) to record their daily pain, mood, sleep, and substance use (alcohol, caffeine, prescribed and over the counter medication, heating pads, ice packs, etc) while they sleep ad lib at home, following their usual sleep schedule. They will then undergo pain sensitivity testing (acute pain induction with forearm ischemia and heat, between noon-1pm as per our pilot). On Day 8 (lab visit #2) subjects will complete questionnaires, have their diaries and wrist actigraphy data reviewed and then will undergo pain sensitivity testing again. Following this subjects will be trained in home saliva collection, receive a kit to take home and will complete their saliva collection that night. The following morning (Day 9, home visit #1) two research staff (mixed gender team) will visit the subject in their home to set up and instruct the subjects in the bright light treatment, and collect their saliva kit and samples. Subjects will self-administer the bright light for 1 h/morning for 6 days before returning to the lab (Day 15, lab visit #3) for repeat questionnaires, review of their diaries and wrist actigraphy, pain sensitivity testing and issuing of the saliva collection kit. Research staff will again visit their homes to collect the saliva kit and samples (Day 16, home visit #2). After a further 7 days of bright light treatment, subjects will return for their last lab visit (Day 22, lab visit #4) for questionnaires, review of their diaries and wrist actigraphy, repeat pain sensitivity testing and issuing of the saliva collection kit. The following morning on Day 23 another home visit (home visit #3) will occur, and research staff will collect the light boxes, saliva kit, samples, and wrist monitors. The PDAs for electronic diaries will be left with the subject. During a 1 month follow up after cessation of the bright light treatment, subjects will continue to report their pain, mood and sleep once a day on the electronic diaries (once a day only to reduce burden and improve compliance). At the end of the follow up staff will collect the PDAs with electronic diaries during a final home visit.

**Amendment 3:** there will be 1 more lab visit, approximately 2 weeks into the 30 day follow up to enable us to download data from the e-diary. We will schedule this extra lab visit at a date and time convenient to the veteran to reduce their burden.