8. Chapter 8: Adherence and Retention

8.1 Introduction

The merit of the COMBINE scientific endeavor rests on collection of the most complete and accurate data possible. Every effort to increase adherence and retention is of a necessity.

Problems in adherence and retention are linked to 3 distinct phases: a) recruitment, b) medical and psychosocial treatment, and c) post-treatment follow-up assessments/interviews. This chapter outlines problems and solutions pertaining to the recruitment and follow-up phases. Problems and solutions linked to the treatment phase are addressed in Chapters 5 & 6 of the protocol.

8.1.1 Boundaries between the Data Collection and Treatment Arms

There is a clear distinction between the treatment and the data collection phase of the trial. The importance of the separation between the two phases is embodied in the fact that different staff perform these two vital functions. Staff collecting data should be trained in respecting and maintaining this distinction. Staff should also acquire skills and resources to deal with situations that challenge the boundaries between the treatment and data collection phases.

Research Assistants who establish therapeutic relationships with the participants risk the contamination of the data and the provision of good clinical care. Research Assistants should be given support in responding humanly and compassionately to participants' distress. However, when the participant asks for personal advice, describes situations where advice is needed, or shows signs of acute distress, Research Assistants should forward the case to the appropriate staff (supervisor, therapist, PC etc.) as delineated in the Communication Grid (Appendix B).

The division of responsibilities between clinicians and data collection staff during the active course of treatment is defined so that serious issues that arise with the participant are referred to the trial therapist. When the active treatment is over, however, the situation becomes more difficult. The participant who – most likely - has established a good rapport with the research staff may use follow-up contact as ample time and opportunity to raise personal issues. Moreover, at this phase of the study, the participant may confuse data collection activities with aftercare services. It is important for the Research Assistant to identify the risk of crossing boundaries and to present such cases to the supervisor or Project Coordinator who will then refer the participant to a trained professional.

Research data must be collected regardless of the participant's involvement in treatment. The Research Assistant must understand and convey to the participant that data collection follow-up sessions will continue throughout the course of the trial even if a participant chooses to leave treatment. In this regard, it is important to note that a randomized participant should not be regarded as ever dropping out of the study.

8.1.2 Principles and Guidelines that apply to Recruitment and Post-Treatment Follow-Up Assessments/Interviews

- Compliance and retention in the study begin with the very first contact with a potential participant
- Every step of the process must be understood by the participant to ensure commitment for the entire study
- Since study staff has an understanding of the entire study, the compliance contract between the staff and the participant is more the responsibility of the staff
- Participants should **never** be regarded as dropping out of the data collection phase of the trial
- Noncompliance is assumed to result from a variety of sources including individual, interactional, and contextual; an understanding of the sources can decrease noncompliance
- The majority of participants pose few problems; the few that do present problems require a standardized – though somewhat flexible - approach to adherence and retention
- Although retention in one phase influences retention in another, drop-out from one phase does not necessarily imply drop-out from another; participants can be lost, resistant, or refusing additional contact and each of these types requires standardized decision rules for management
- Contact must be maximized throughout the entire study in order to ensure complete and accurate data
- Research staff should keep in mind that participants who are incarcerated should not be contacted without the site first fulfilling additional IRB requirements concerning research with incarcerated persons.

General principles of adherence and retention during the treatment phase of the study are described in the treatment manuals. The following sections apply to the window of time between the initial contact with the participant through initiation of treatment, and then post-treatment follow-up assessments/interviews.

8.2 "Early Warning System"

Gilbert and Maxwell (1987) suggest an "early warning system" that alerts study staff when a participant is at high risk for dropping out. They indicate that knowledge of an individual's status in treatment can substantially reduce the error in predicting attendance at follow-up evaluations. An early warning system for increased risk of losing participants will allow staff to take actions that will minimize data loss at follow-up. Because many of the interventions designed to reduce participant dropout consume staff time and resources, use of enhanced retention procedures should be tailored to the level of risk for non-adherence. Although a standardized plan for addressing all risk factors may not be practically feasible, general guidelines that can be implemented on a case-by-case basis will help to improve cross-site consistency and reduce the likelihood of permanently missing data.

8.2.1 Enrollment, Treatment, and Follow-up Risk Factors

The first step in implementing an enhanced retention strategy is to have a means for assessing, tracking, updating, and accessing the information that will be used to determine the overall risk of non-adherence. The following is a list of some potential risk factors that may be associated with future non-adherence. Although not all of these indicators signal an immediate problem, use of routine and enhanced retention strategies at the time the warning sign is noted may help to reduce the likelihood of a future problem. See Table 8.1 for a list of risk factors that may be associated with non-adherence during enrollment, treatment and follow-up. These factors may be explicitly expressed by participants or observed by the study staff.

Table 8.1 Enrollment, Treatment, and Follow-up Risk Factors

Enrollment Phase **Risk Factors:**	**Treatment Phase** **Risk Factors:**	**Follow-Up Phase** **Risk Factors:**
Expressed • Concerns about randomization • Expectations for specific treatment • Doubts about medication compliance • Concerns about side effects • Concerns with one or some aspects of the study protocol • Other expressed enrollment risks	Expressed • Dissatisfaction with treatment assignment • Dissatisfaction with treating clinician(s) • Dissatisfaction with medication (side-effects or non-effective) • Difficulty to meet time demands • Other expressed treatment risks	Expressed • Dissatisfaction with services provided • Dissatisfaction with treating clinician(s) • Dissatisfaction with medication • Difficulty to meet time demands • Other concerns expressed during risks
Observed • Re-scheduled screening appointments • No-show for screening appointments • BAC>0 at baseline interview • Extremely elevated liver enzyme GGT • Problems with detoxification • Permanent address is different from current address • Duration of current address is less than 3 months • Plans to move in the next year • Did not see PCP for > 10 years • Other observed enrollment risks	Observed • Re-scheduled treatment appointments • No-show for treatment appointments • Unresponsive to or refusing routine scheduling procedures • Discontinuation of medication with no apparent reason • Manifestation of clinical deterioration • Early drop out from treatment • Plans to move in the next year • Loss of housing • Unexpected social, occupational, or health event • Lost contact (disconnected phone, undelivered mail) • Other observed treatment risks	Observed • Loss of interest in the study due to end of treatment • Clinical deterioration • Plans to move in the next year • Loss of housing • Unexpected social, occupational, or health event • Other observed follow-up risks

8.2.2 Levels of Intervention

In order to successfully implement enhanced retention procedures, a mechanism for systemic tracking of these risk factors needs to be in place for the main trial. Within the Client Tracking Database, there should be a means for recording the presence of each of the identified risk factors and a means for recording what level of risk is present and what intervention was implemented to address this risk. Staff response to these risk factors should be planned on a case-by-case basis using some general guidelines for which procedures to employ at each level of risk. The following are proposed levels of risk for data loss. Routine and enhanced procedures to address each level of risk are outlined in table 9.2.

8.2.2.1 LEVEL 0 – No Risk

In the absence of any of these risk factors or others not listed here, study staff would follow guidelines of the Main Trial Protocol or Manual of Operation employing only routine procedures to reduce non-adherence risks (e.g., mailing reminder letters before each follow-up visit).

8.2.2.2 LEVEL 1- Relocation Risk

Level 1 risk is characterized by a potential loss of data due to difficulties in locating participants at the time a research visit is indicated (e.g., participant plans to move in the next year, loss of housing). At this level of risk study staff should employ the routine procedures outlined in table 8.2, and if necessary employ enhanced procedures with PI or PC involvement.

8.2.2.3 LEVEL 2 – Ambivalent participant

Level 2 risk is characterized by potential loss of data because of participants' concerns or dissatisfaction with treatment or the study in general (e.g., expressed difficulty meeting study time demands). At this level of risk study staff should employ the routine procedures outlined in table 8.2, and if necessary employ enhanced procedures with PI or PC involvement.

8.2.2.4 LEVEL 3 – Absent Participant

Level 3 risk is characterized by loss of data because of missed research appointments due to life stressors (sickness, childcare etc.). At this level, study staff should employ routine and enhanced procedures outlined in table 8.2, and if necessary employ enhanced procedures with PI or PC involvement

8.2.2.5 LEVEL 4 – Refusing Participant

Level 4 risk is characterized by loss of data because the participant is refusing to continue with research interviews or assessments. At this level of risk study staff should employ the routine and enhanced procedures outlined in table 8.2, and if necessary employ enhanced procedures with PI or PC involvement.

8.2.2.6 LEVEL 5 – Lost participant

Level 5 risk is characterized by loss of data because the participant can not be located at the time a research appointment is indicated. At this level, study staff should employ the routine and enhanced procedures outlined in table 8.2, and if necessary employ enhanced procedures with PI or PC involvement. Interventions at each level of risk should not be implemented exclusively as some problems may warrant a response that incorporates multiple interventions. The use of problem-specific interventions not captured by these guidelines should be implemented as needed and be recorded in the Client Tracking Database.

Below is a summary of some practical strategies that may enhance willingness to participate in and adhere to the study until it is completed

8.3 Practical Strategies to Enhance Adherence and Retention

General guidelines to enhance adherence and retention are listed below:

- Positive interactions and good flow of communication between study and site staff will facilitate referral to the project

- Identification of study personnel with whom to consult and problem-solve will support and enhance adherence and retention

- Staff selection and training is very important

- Roles and responsibilities for each staff should be clearly defined

- Periodic meetings of study personnel will help to build a strong team and facilitate communication

- Potential participants should be informed of the study specifics in a manner that increases willingness to participate. For example, benefits of participation should be highlighted, incentives for study participation and retention should be clear and participants should also be alerted to inadvertent non-compliance with assessment procedures. All such techniques should be comparable across sites to minimize site differences.

- Research assistants and assessment personnel should identify and remove barriers to assessment completion. The suggestions listed below present the challenge of enhancing compliance with the study while minimizing protocol deviations. A reasonable rule of thumb is that some data are better than no data. For example, data that should be preferentially collected are those that will be used in calculating primary and secondary endpoints, such as Form 90 and the related calendar. These guidelines must be balanced by employing a good scientific judgement against the importance of protocol violations:

  - Provide cultural sensitivity training to all staff
  - Be flexible in scheduling assessments on early morning, evening, or holidays. Check with participants about best days and times to come in. Try to schedule MM, CBI, and RA visits on the same day for the participant's convenience.
  - Provide local bus schedules and telephone numbers for taxi service
  - Prepare waiting areas for family members that accompany participants

- Research staff are encouraged to send participants holiday and birthday cards, as these are ways of keeping in touch and of expressing appreciation for participant's involvement.

- When the participant provides locator information, it is important to verify that the locator is a real person who can be reached. Suggested methods of verifying locator's existence include calling the locator while the participant is in the office and sending the locator a letter co-signed by the participant and study staff (participant's permission is required for both methods).

8.3.1 Guidelines for Telephone Contact

- Make a reminder call the day before each follow-up visit.
- Continue to make phone calls for those who fail to show for the study visit. If cannot be reached by phone, the participant's locator should be contacted.
- Document each phone call/contact and its results. If an answering machine is reached, it is a good idea to attempt calling again in order to speak with a person. If someone other than the participant answers record the person's name and relationship to the participant. This information helps determining the feasibility of leaving another message with the same person. It also helps getting convenient times to reach the participant or a change in his/her schedule.

8.3.2 Guidelines for Mail Contact

Letters to participants should have an easily identifiable logo matching the logo on the business cards. Letters should be designed with care to exclude information that would compromise the participant's confidentiality. Typically, letters should provide study information that may be of interest to the participants and reinforce a sense of belonging to the study.

Any mail should include a return address, along with the letters ACRDNF (Address Correction Required, Do Not Forward). This alerts the post office to return the unopened mail with a new address listed if one is available. The post office will forward first class mail for 12 to 18 months provided an address has been given. They will notify the sender of a new address for 1 year. They will forward second class mail for 60 days. If there is no forwarding address available, it will be noted as "Moved No Forwarding Address". Participants who are about to relocate could be sent a change of address card, and be given a small incentive for returning the card.

All correspondence should be recorded in details in the Client Tracking System. Copies of correspondence sent to participants should be filed in separate and confidential charts. The following strategies are recommended:

- Remind participants of their visit by sending a letter one-week before each follow-up visit.
- Send brief letters at regular intervals during the follow-up phase to maintain contact with the participant between study visits.

Send registered mail to the most recent address of the participant if a) a participant fails to show up for a study visit, b) is not reached by phone and c) the locators do not know the whereabouts of the participant.

8.3.3 Specific Guidelines for Informed Consent Procedures

Specific guidelines for the informed consent procedures are listed in Chapter 4 (Baseline) of the Manual of Operations. An Informed Consent Checklist (located in Appendix B) should be followed during the informed consent procedure. When talking with participants about contacting them in the future, sites might want to have a list of options of how staff will contact them (i.e., ok to leave message? ok to e-mail? - let person know that this may not be completely confidential. This list may come in a "contact sheet" format that has all the contact options and the participant checks off options with which he/she is in agreement.

8.3.4 Specific Guidelines for Baseline Interviews

Guidelines for the baseline interview conducted by Research Assistants are located in Chapter 4 (Baseline) of the Manual of Operations.

8.3.5 Specific Guidelines for Informing Participant of Treatment Assignment

Guidelines for informing the participant of their treatment assignment are located in Chapter 5 (Randomization) of the Manual of Operations.

8.3.6 Specific Guidelines for Increasing Financial Incentives

In general, sites should adhere to the reimbursement schedule indicated in the protocol. In certain cases, an ambivalent or resistant participant may be willing to complete research assessments upon being offered additional financial incentives. These incentives should not exceed $125 per participant for the whole study, and should be used only if the other strategies for re-engaging the participant have not been successful (see Table 8.2). Thus, it should not be assumed that each participant is eligible for financial incentives. Rather, the PI (or another staff person designated by the PI) should be consulted in each case that a financial incentive is considered. The PI and the other site team members should decide how much money to offer the participant. Financial incentives may be used for direct payment or other purposes such as reimbursement for transportation or baby sitter fees. Sites must check with their IRBs to find out whether this strategy is allowed and whether IRB approval is required. The informed consent form does not need to be changed to accommodate the possibility of increasing financial incentives, but the site IRB must approve this procedure.

8.3.7 Specific Guidelines for Provision of Public Transportation

According to the protocol, participants are responsible for their transportation. This should be clarified at the time of signing the informed consent. However, it is possible that once the participant has been enrolled, lack of adequate transportation may contribute to his or her ambivalence or refusal to continue participation. Each site should develop specific guidelines for providing participants with transportation options such as reimbursement for parking or bus fare, and provision of taxi services. In the latter case, arrangements should be made to pay the driver directly to prevent misuse of the system. Money for transportation has to come from the $125 financial incentive described in section 8.3.6. Sites must ensure that their IRBs approve of this procedure.

8.3.8 Client Tracking Database

A tracking system is essential for enhancing adherence and retention and should be utilized on an ongoing basis and updated regularly. The Client Tracking Database will consists of several data sets:

- **Pre-Randomization Screening and Difficulty with Enrollment**

The screening portion will assist with identification of participants' characteristics and evaluation of generalizability. Information will include the following information:

- Participant ID and initials
- Recruitment Resource
- Gender
- Race
- Age
- Reason for ineligibility

The Difficulty with Enrollment portion will act as an early-warning indicator for post-inclusion adherence problems. Enrollment and treatment risk factors (expressed and observed) outlined in Table 8.1 of this chapter will be tracked.

- **Participant and Locator Contact Information**

The tracking system will maintain contact information (i.e., day and evening phone numbers, beeper, cell phone, permanent-mailing address of the participants and locator(s), etc.). Information should be updated regularly.

- **Post-Randomization Client Tracking**

This portion of the system will assist in monitoring the flow of participants throughout the study. It contains:

- Participant ID and initials
- Assessment “due dates”
- Scheduled appointment date
- Actual appointment date
- Schedule window (3 days on either side of the due date)
- Attendance

- **Post-Randomization “Routine and Enhanced Procedures”**

The Client Tracking Database will also track information about participants that are 1) absent, 2) ambivalent, 3) refusing or 4) lost and the types of strategies (i.e., interactive, adaptive, “cracked door”) that were implemented in order to re-engage the participant. Table 8.2 outlines the strategies that are implemented with respect to the participant’s status.

- **Contact with Participant**

When research staff correspond with a participant or locator outside of the scheduled research visits (i.e., phone, mail, etc.), this information should be recorded and entered into the tracking system. This will allow staff to determine when the next contact should take place as well as types of contact that have been successful.

- **Incentives**

The amount and type of incentive given to the participant will also be entered the tracking system. If part of the re-engagement strategies involve increasing the participant’s incentives, this amount should be entered as well.

8.4 Non-Adherence: Active and Inactive Status

8.4.1 Research Inactive Status

Definition: Participant who misses one research assessment/interview

- Inactive participant should not be viewed as dropping out of the study

- Participants can be designated research inactive status several times throughout the course of the study
- Participants can also be designated inactive in MM and/ or CBI; this procedure is described in each of the treatment manuals

8.4.1.1 Re-engaging Strategies

When a participant becomes inactive, the Research Assistant should determine the inactive status type and proceed with the recommended strategies listed in this chapter. The following are general guidelines to be followed regardless of the particular inactive type designated to the participant:

- Call participant to find out their standing with participation in the study
- Explore reasons for not wanting to participate
- Inform participant that research visits can be resumed at any time
- Re-iterate number of research visits that still need to be completed
- If the participant indicates that they will not be coming back to the research visits, collect the following information, in order of importance by phone or in-person:

  →Drinking Data (Form 90, TLFB)
  →Safety Data (SAFTEE)
  →Compliance Data (Pill Count, Medication (Non)Compliance Checklist)
  →Inactive Status Information (Inactive Status Form part B)

8.4.2 Resuming Active Status:

Definition: An inactive participant that resumes research visits is considered active.

8.5 Inactive Types: Absent, Ambivalent, Refusing, or Lost Participants

Participants may chose to terminate all association with the study. Ultimately, this choice must be respected. However, in most circumstances it is unwise to take the first expression of a participant's wish as the final decision. Four inactive types are identified in this chapter: absent, ambivalent, refusing or lost participant.

8.5.1 Absent Participant

Definition: On-going or intermittent contact is maintained but the participant is unable to attend the research appointment due to life stressors (i.e., sickness/injury, child-care etc.).

8.5.2 Ambivalent Participant

Definition: On-going or intermittent contact is maintained but the participant is ambivalent with, or resistant to, study participation.

8.5.3 Refusing Participant

Definition: On-going or intermittent contact is maintained but the participant refuses to participate in the study.

8.5.4 Lost Participant

Definition: Contact is not maintained and the participant does not attend the research appointment(s).

8.6 Routine and Enhanced Procedures for Inactive Types

A distinction is made between routine and enhanced procedures. Routine procedures consist of techniques that aim at maintaining working alliance and good rapport with the study participants. The routine procedures are congruent with the Main Trial Protocol and are used on all participants across all phases. The enhanced procedures, on the other hand, are non-routine techniques designed to prevent drop out when a warning sign is indicated or to re-engage participants when there is a clear indication of study withdrawal. Enhance procedures may consume staff time and resources and their use should be tailored to the level of non-adherence risk or to the particular inactive type that characterizes the participant. Special attention should be paid to contacting refusing participants. Participants who state that they do not want to be contacted must not be contacted. Contacting these participants is disrespectful and may result in an IRB complaint.

The following sections outline three types of strategies that research staff should use when a participant is designated inactive: a) interactive strategy, b) adaptive strategy And c) “cracked door” strategy. It should be noted that interactive and “cracked door” strategies consist of both routine and enhanced procedures whereas adaptive strategies are exclusively enhanced. Barrett and Morse (1998) suggest that non-routine or enhanced procedures should be used for exceptional cases and be carried out incrementally because they may represent a greater deviation from protocol.

8.6.1 Interactive Strategies

The MATCH Monograph identifies the following interactive strategies: a) meet resistance with understanding, empathy, and respect, b) normalize or legitimize problems with the study, and c) provide a rationale for involvement and a range of possible solutions. Based on these strategies, guidelines for interactive strategies for COMBINE include:

- conduct regular discussions among research staff as well as between research and clinical staff to clarify roles and responsibilities and to strategize about optimal ways of interacting with the specific participant
- adopt an understanding, empathic, and respectful stance and show genuine interest in knowing why the participant wishes to drop out
- offer a sympathetic ear to a participant who initiate a conversation about his/her life difficulties or about the lack of support they receive from their network (i.e., significant other, AA, friends); however, AVOID engaging in further discussion and refer the participant to the PC or PI who a) may be more experienced in this domain and b) has less frequent interactions with the participant

Participants may chose to drop out for a variety of reasons. They may have the perception that they have given the same information over and over again. They may complain that the treatment is not effective because their drinking has not improved or that treatment is not warranted any more because they are able to abstain from drinking. Participants may also think that their contribution to the study is minimal. For these or other reasons, participants may lose interest in the study. If a participant expresses reservations about continuation of the study, the research staff should respectfully listen to these reservations and use the following techniques:

- **Emphasize the participant's importance to the study regardless of drinking status**
- **Normalize the phenomenon of losing interest in the study**

- **Arrange a meeting between the participant and the PC and later the PI to:**
  - a) **identify obstacles to compliance**
  - b) **Engage the participant in active problem-solving**
  - c) **Offer help with problems that may be an obstacle to compliance**

8.6.2 Adaptive Strategies

Participants can become uncomfortable with various aspects of the study. For example, participants may have concerns about the time commitment or they may have transportation or other constraints that prevent their active participation in the study. On a general level, it is important to identify the reasons for non-adherence and to address them by allowing flexibility with the study procedures.

Adaptive strategies are aimed at removing obstacles that some participants may encounter throughout the study. As already noted, adaptive strategies consist of enhanced procedures exclusively and they represent greater diversion from the Main Trial Protocol. It is recommended to utilize an adaptive strategy after exhausting all interactive strategies. Furthermore, the adaptive techniques should be used incrementally in the order that they are listed below:

- **Allow flexibility with scheduling during weekends or holidays**
- **Do not tape the assessment if confidentiality is an obstacle**
- **Reimburse for parking**
- **Provide taxi service but pay the driver directly to avoid potential misuse of the system**
- **Offer extra money for baby sitter**
- **Conduct phone interview**
- **Make home visit but send two Research Assistant for safety reasons**
- **Increase financial incentives (See 8.3.6)**
- **Obtain partial data including vital forms only**

8.6.3 "Cracked Door" Strategies

The “cracked door” strategies are applicable when all interactive and adaptive techniques fail to re-engage a participant in the study. Indeed, some participants may wish to drop out of the study for a variety of reasons. Under these circumstances, the research staff is facing two challenging tasks: a) overcoming discouragement and frustration of the staff member who had already invested time and efforts in re-engaging the participant and b) maintaining ongoing contact with a participant whose stance is determinant and adamant. The following techniques are suggested:

- **Request permission to re-contact at a later time**

The art is to avoid eliciting a ‘NO’ response. Examples include:

- "It sounds as though today is not a good day for you to complete the interview. How about I give you a call next week and see if we can find a more convent time?"
- "Thank you for your participation so far and for coming in today. I respect your wishes not to finish the interview today. Would it be okay if I called you in a few weeks and just check in?"

Another option is to thank the person for coming and not ask at that moment whether or not you can reschedule an interview. Perhaps it might be more effective to:

- follow-up with a thank you letter and mention that the research staff will try to call them and see if they have changed their mind
- follow-up with a phone call only

- **Refer the matter to the PC/PI**

  - Sometimes, referring the individual to another staff member, especially the PC or PI, may be helpful in changing the participant's stance. Project Match (Monograph 7) suggests that the Research Assistant indicate that he/she does not have the authority to "dissolve the research agreement" and request that the participant speak with the PC/PI. This strategy serves several purposes:

    1. Emphasizes the importance of the decision and the value of the participant's contribution to the study
    2. Provides participants with another opportunity to rethink their decision
    3. A person of greater authority may be able to more effectively address the concerns of the participant.

In some cases, it may be best to proceed with immediate referral to the PI. There are several reasons for immediate PI referral. First, the participant may have already spoken with the PC about the issue, or may want to speak to the PI about the PC. Second, it may be difficult to convince a refusing participant to attend two separate meetings or to speak with two different people. Given that the PI may be seen as the person with more authority, it may be more efficient to proceed with setting up a meeting/phone call with the PI. However, the preferred procedure may be site-specific. Before referring the participant to the PC/PI, the following information may facilitate a smooth hand-off:

- familiarity with the participant's reason(s) for not wanting to participate, and
- the perception/speculation of the Research Assistant of the participant's reasons to drop out of the study

- **If all efforts fail, accept situation gracefully**

If, despite all best efforts, the participant refuses to re-engage, accept their choice. Thank them for their participation thus far with a thank you letter signed by all members of the research team. Also, let the participant know that she/he can come back at any time, and ask if it is possible to mail study materials periodically.