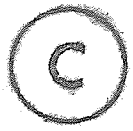
THE UNIVERSITY OF MANITOBA

EFFECTS OF A BEHAVIORAL SELF-CONTROL PACKAGE ON DRUG PRESCRIPTION COMPLIANCE BEHAVIOR OF CHRONIC ARTHRITIC PATIENTS

by



L. Craig Turner

A Thesis

Submitted to the Faculty of Graduate Studies

In Partial Fulfillment of the Requirements for the Degree

of Doctor of Philosophy

Department of Psychology

Winnipeg, Manitoba

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ABSTRACT

The present study examined the effectiveness of a behavioral self-control package (i.e., alarm watch, cue cards, self-monitoring, & self-reinforcement) upon the medical compliance behavior of chronic arthritic patients. Compliance was assessed by pill counts, blood serum levels, physiological measures (e.g., degree of joint swelling and stiffness, pain level assessment, grip strength), and self-monitoring data sheets. A group of 21 rheumatoid arthritic patients, starting a new drug study, were chosen as the subject pool. All subjects received both ASA and the new drug Piroxicam but they were blinded as to which medication was active and which medication was placebo. Baseline compliance was assessed for these 21 patients over a 5 week period, with the four least compliant subjects receiving the self-control package. The package was introduced in a multiple baseline across subjects design. At the end of 12-15 weeks three of the subjects were placed on a 1 month follow-up phase (one subject had been discontinued earlier due to medical difficulties). Results showed high rates of compliance to Piroxicam and quite variable rates to ASA (which required ingestion of more pills) during baseline. During treatment however, high, almost perfect rates of compliance were attained for both Piroxicam and ASA and were maintained for the duration of treatment. Follow-up data showed aconsistent maintenance of these high rates for each subject's active medication. Despite varying degrees of severity of noncompliance the self-control package was found to be equally effective. Finally, the social validation questionnaire, which was given to the subjects at the completion of the study showed that they found the package to be quite helpful although they differed in their opinions as to which components were the most useful.

Acknowledgements

I would like to take this opportunity to thank my committee members for their excellent support and guidance during the running of this research. I owe a great deal of thanks to my advisor Dr. Steve Holborn whose continual advice and encouragement helped to get this research started and completed on time. Dr. Joe Pear who was my advisor during my master's research continued to offer me his assistance during this current research. Dr. Glen Lowther who also served as a committee member for my master's research as well as this present research. He gave unselfishly of his time and also became one of the major forces in securing employment for me over these several years which enabled me to continue with my education. Dr. Bruce Masek, who served as my external examiner, gave my thesis his prompt attention under most difficult circumstances.

I would also like to thank my final committee member, Dr. Garry Martin. Back in 1972, as an undergraduate, I made some rather random choices of psychology courses for that year. In those choices were two half courses taught by Dr. Martin. It was through his excellent teaching style and honest concern in a student's development that made me a convert to the Skinnerian way of psychology, namely behavior modification. From that point on Garry has served unofficially as my advisor and my guiding light. Garry, I owe you a debt that I will never be able to repay but as a start I would like to dedicate this thesis to you as a very small sign of my appreciation. I can't thank you enough.

Now in terms of the actual running of my research if it wasn't for a chance meeting with an old high school alumnus, Dr. Brian Penner, who worked in the Health Sciences Centre, I would never have been introduced

to the right people, and my research probably would never have gotten off the ground. Thank you Brian.

One of those individuals who Brian introduced me too was Dr. Fletcher Baragar, Head of Rheumatology at Health Sciences Rehabilitation Centre. It was through Dr. Baragar's genuine interest in me and my research that allowed me to conduct my research. For this I also owe Dr. Baragar a great deal of thanks. A second major source of help for me at the Rehabilitation Centre was Janice Howorth, the physiotherapist involved in the drug study. I appreciated all that you did to help me Janice.

Finally, I owe immeasurable thanks to the members of my family. Barb and Gord for their interest and concern in my education over all these years. To Teresa, who is to become my wife in a few short days, has unfortunately had to bear the brunt of a lot of my anxieties and frustrations during the preparations and especially the conclusions of my research. You will never know how helpful your love and support has been to me in this past year. This at last takes me to my parents, Fred and Gertrude. Your constant love, advice, and support were always needed, although perhaps not always given the recognition they deserved. Now that I am finally approaching the end of my academic education and starting out into the "real" world I can now perhaps start to repay you. I also dedicate this thesis to you both as a begining on that debt. I love you both very much.

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Behavioral Medicine*

There is a growing awareness today among behavioral psychologists, medical practitioners, and the general public regarding the role of behavioral factors in the etiology, treatment, and prevention of disease. The outcome of these concerns is a rapidly expanding field of research called behavioral medicine.

The term behavioral medicine may be defined as: "(a) the clinical use of techniques derived from the experimental analysis of behavior-behavior therapy and behavior modification - for the evaluation, prevention, management, or treatment of physical disease or physiological dysfunction; and (b) the conduct of research contributing to the functional analysis and understanding of behaviors associated with medical disorders and problems in health care" (Pomerleau & Brady, 1979, p. xii).

One of the principal lines of development in behavioral medicine is the intervention to modify adherence to prescribed treatment. Pomerleau (1979) states: "There has been a growing awareness that the failure of patients to adhere to a prescribed medical treatment is probably the single greatest problem in providing effective medical care" (p.659). As for the magnitude of the compliance problem, current estimates are that between 20% and 80% of patients do not follow their regimens, with an average of only 50% of patients on long term medication or diets compliant (Pomerleau, 1979).

In a review of the behavioral medicine literature only a few studies were found which focused on the patient compliance problem. One of these, a study by Miller, Hersen, and Eisler (1974), analyzed the effects of instructions, behavioral contracts, and reinforcementupon compliance behavior of 40 chronic alcholics. Results indicated that while instructions and behavioral

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* See Appendix A for a more extensive review of the behavioral medicine-patient compliance literature.

contracts had limited influence on drinking, both groups receiving therapist-reinforcement for compliance significantly decreased their operant drinking behavior.

Four studies (i.e., Dapcich-Miura & Hovell, 1979; Lowe & Lutzker, 1979; Magrab & Papadopoulou, 1977; Renne & Creer, 1976) have examined the effects of token reinforcement upon eight types of compliance behavior. Dapcich and Hovell (1979) were concerned with exercise, orange juice consumption, and pill taking with a coronary patient; Lowe and Lutzker (1979) were concerned with diet, foot care, and urine testing with a juvenile diabetic; Magrab and Papadopoulou (1977) were concerned with diets for patients on hemodialysis; and Renne and Creer (1976) were concerned with teaching the proper use of intermittent positive pressure equipment to asthmatics. All four studies found therapist-controlled reinforcement procedures to be effective in improving compliance behavior.

A recent study (Epstein & Masek, 1978) is interesting for two reasons. The previous studies all used therapist-controlled reinforcement and monitoring procedures. None of the studies reviewed had assessed the effect of self-control techniques on compliance behavior. Epstein and Masek's investigation appears to be the only one which attempted to include self-control procedures (i.e., self-monitoring). The authors compared four groups of college students and their levels of compliance in taking Vitamin C tablets. The groups were: (1) self-monitoring (i.e., the subjects were required to record the time at which each medical dosage was taken); (2) taste (i.e., subjects were provided with flavored pills); (3) taste plus self-monitoring; and (4) no treatment control group. Subjects also monitored time of urine discoloration produced by a chemical, phenazopyridine, in selected pills.

The results of the first phase of the study showed insufficient

control of compliance behavior with the self-monitoring groups (i.e., self-monitoring and taste plus self-monitoring) having only slightly higher levels of compliance than the remaining two groups (i.e., taste and no treatment control). Due to the limited control of compliance behavior, response-cost procedures were introduced (i.e., $1.00 of a total deposit of $9.00 would be forfeited each week in which subjects did not score two or better). Since the subjects received three tracer pills each week, a compliance score of three indicated agreement on all three tracers between the subject and the experimenter as to the time of urine discoloration appearance. Conversely, a compliance score of zero meant that the subject and experimenter failed to agree on any of the urine discoloration times. Similarily, scores of one and two represented one-third and two-thirds agreement respectfully. The results showed a sharp increase in compliance for all subjects with the self-monitoring plus response-cost group having the highest level of compliance.

Several points about this study require elaboration. First the use of urine tracers in the medication (which the authors gave out in a predetermined schedule) appears to be a much more accurate measure of compliance than the traditional patient self-reports and pill count techniques. Future medication compliance research should further examine this technique. Second, while the authors did use a form of self-control (i.e., self-monitoring), reinforcement was totally controlled by the therapist (i.e., no self-reinforcement). Third, the introduction of the response-cost procedure has a serious confound. Prior to the introduction of response-cost the subjects were unaware that their medication compliance behavior was being monitored. When the response-cost procedure was explained, it

became apparent to the subjects that the researchers had some method of determining whether they took their pills or not. Thus the resultant increase in the mean compliance scores of the subjects may have been due to either the monitoring evaluation or the response-cost or both.

One of the recommendations for future directions in improving medical compliance is to make more use of self-control techniques (Pomerleau, 1979). As previously acknowledged, Epstein and Masek (1978) appear to have conducted the only study in the behavioral medicine literature to approximate this recommendation. Considering that self-control techniques have been used successfully in obesity therapy (e.g., Mahoney, 1974; Stuart, 1967; Wollersheim, 1970), which can be considered to fall under the behavioral medicine paradigm, researchers in the patient-compliance field should seriously examine these techniques. However, before self-control procedures are discussed, there are several methodological concerns of vital importance when investigating patient compliance.

Methodological Concerns for Behavioral Medicine Research

The development of reliable and valid assessment techniques has been a major consideration in the field of behavior analysis (Russo, Bird, & Masek, 1980). The melding of behavior analysis and medicine must have similar considerations. Unfortunately though, this does not presently appear to be the case. Behavioral analysis or behavioral science traditionally has been disinterested in internal causes and mechanisms. Philosophically, the prime concern of behaviorism has been measurement of observable behavior. An explicit disinterest in underlying causes of psychiatric and behavioral disorders has been promoted (Bandura, 1969), and contrasts

between behavioral and medical views of pathology have been emphasized (e.g., Ullman & Krasner, 1965). Single-subject research methodology has been espoused, without major concern for behavioral epidemiology (Epstein & LaPorte, 1978) emphasizing instead behavioral outcome and the potency of treatment effects (Hersen & Barlow, 1976).

In contrast to behavioral science, the discovery of internal causes and mechanisms of disease has been and will continue to be a major goal in biomedical research. Biomedical science is strongly committed to the validation of measures in the search for underlying mechanisms. However, objectivity and reliability, especially of behavioral observations, are often assumed, and are not directly assessed in medicine.

In terms of methods by which data are collected, behavioral science is based on assessment of the temporal relationships between changes in the environment and changes in the dependent measures. On the other hand, in biomedicine many physiological and biochemical responses are assessed long after interventions occur, with little attention to the environment (Russo et al., 1980).

There appear to be three types of behavioral reliability problems which have direct impact on the quality of both medical research and treatment (Russo et al., 1980). First, in the physiological and biochemical measures that are often taken, there are poor test-retest reliabilities, especially in those assessment procedures which are complicated and rely upon the proficiency of the technician. Second, there are reliability concerns in assessing the influence of behavior on disease, and in assessing behaviorally-expressed symptoms. Unfortunately, traditional

medicine has continued to view the physician's assessment and manipulation of behavior as an "art" and not as a "science" (Engel, 1977). Russo et al (1980) believe that the solution to this problem lies in educating medical collegues through rigorous demonstrations of the available technology. Third, the issue of reliability is central to the study of compliance behavior in patients. The literature on compliance with medical regimens illustrates some of the methodological developments resulting in more reliable assessments of medication ingestion (Russo et al., 1980).

Traditionally, compliance research has employed a variety of measures (e.g., self-report, pill counts, urine tracers and urine or serum bioassays). Self-report has been found to be the least reliable measure as several studies have discovered (e.g., Park & Lipman, 1964; Rickels & Briscoe, 1970). Giving patients an oversupply of medication and having them return those pills unused has also been utilized frequently, but this measure also has reliability problems (Roth, Caron, & Hsi, 1970).

The urine or serum bioassay for a drug or its metabolites is certainly more objective than the previous two procedures but, as was previously mentioned, it has been plagued by poor test-retest measures. Besides the reliabilities of technicians' abilities, urine or serum bioassay methods have other problems. Not every drug can be readily detected in the serum or urine, and fine grained analysis of compliance dosage schedules can not be done with this technique, since it is impossible to determine when a drug was consummed based simply upon the presence of the drug in the urine or serum.

Because of these problems, the application of more reliable behavioral assessment measures in this area has great potential. The studies which have

used more reliable assessment procedures have included direct observation of medication ingestion (Bigelow, Strickler, Leibson, & Griffiths, 1976; Haynes, 1973), and the use of mechanical devices such as a portable operant device which indicates time to take medication by a tone and then dispenses a pill (Azrin & Powell, 1969). However, these studies would be very costly in the natural environment as well as presumably hindering any hope of generalization. A more recent technique designed to constitute a more reliable assessment procedure was Epstein and Masek's (1978) use of chemical tracers in a specific number of the pills given to their subjects. Certainly the use of chemical tracers appears to be the most unobtrusive and comparatively reliable method of these three techniques,but it is becoming increasingly difficult to get approval from governementdrug agencies to use this type of measurement technique.

Considering the reliability problems of measures such as pill counts and urine or serum bioassays, future medical compliance research investigators should not continue to rely solely on the use of one of these measures as their only dependent measure. An argument can be made, it seems, that until a more reliable measure is found, future investigators should combine as many of these compliance measures as possible and use them all as indicators of compliance behavior.

Finally, within the area of medical compliance there is another issue which needs to be discussed. In drug research studies noncompliance to the prescribed medication(s) can be a serious problem. There is evidence to suggest that the results of many published trials of drug efficacy may require reanalysis because medication compliance was not reliably assessed (Blackwell, 1972; Soutter & Kennedy, 1974). Therefore,

in a drug research study, medical compliance behaviors of the subjects should be of paramount concern.

Self-Control*

For the purposes of the present research self-control will be defined as the process by which an individual alters the probability of one of her/his responses by altering the variables of which that response is a function (Skinner, 1953). Skinner goes on to say that self-control entails performing a behavior which manipulates the environment in such a way as to affect the probability of a target behavior or the controlled response.

Since Skinner's original formulation of self-control, several other definitions have been proposed. Thoresen and Mahoney (1974) proposed a definition that conveys the general view reflected in the literature. They suggested that self-control is evident "when in the relative absence of immediate external constraints, a person engages in behavior whose previous probability has been less than that of alternatively available behaviors" (Thoresen & Mahoney, 1974, p. 12). But as Jones, Nelson and Kazdin (1977) and Kazdin (1978) point out, the self-control literature shows a great deal of variability in the use of external variables (e.g., therapist contact, therapist controlled reinforcement).

Problems of self-control usually fall into one of two categories, behavioral excesses or behavioral deficits (Kanfer & Phillips, 1970). In the first category, subjects engage in a behavior pattern that is self-defeating or injurious (e.g., obesity, excessive smoking and drinking). In the second category, subjects suffer because they engage in

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* See Appendix B for a more extensive review of the self-control literature.

certain behaviors only very infrequently (e.g., inability to study, sexual activity). Patient compliance would therefore fit into this second category.

Self-control treatment procedures have been usefully conceptualized in a three-stage model (e.g., Kanfer, 1971; Karoly & Kanfer, 1974). The three phases are: (1) self-recording (also known as self-monitoring), (2) instructions, and (3) self-reinforcement. I shall now discuss these three self-control components.

Self-Recording. Self-recording refers to observing and recording aspects of one's own behavior and has been identified as the crucial first step in the acquisition of self-control skills (Thoresen & Mahoney, 1974). Self-recording, like external monitoring, can involve any number of responses to be recorded as well as various ways to record them. Both the target responses and the self-recording responses can vary from the simple (e.g., recording a check for each problem finished) to the complex (e.g., describing a behavior, its consequences and its antecedents). The self-recording literature suggests that while some studies have found positive results when self-recording is used alone (e.g., Broden, Hall, & Mitts, 1971; Herbert & Baer, 1972), there also have been inconclusive results (e.g., Mahoney, 1974; Nelson, 1977).

Instructions. The second component of a typical behavioral self-control package is the use of written instructions. This component utilizes the effectiveness of posted instructions in the subject's environment to change some aspect of her/his behavior. Generally, these posted instructions are used in conjunction with other procedures such as performance feedback systems (e.g., Van Houten, Nau, & Marini, 1980) but

instructions have been found to be effective by themselves for a limited number of behaviors (e.g., Lowe & Lutzker, 1979).

Self-Reinforcement. This third component of a typical self-control package occupies the most prominent position in various theoretical analyses of self-control (Jones et al., 1977). However, the entire area of self-control and self-reinforcement have been discussed and debated a great deal. Many researchers feel the term self-control is a misnomer and inherently misleading and should be replaced with some other less value-laden term such as self-management (e.g., Brigham, 1980). Other researchers meanwhile, take exception to the term self-reinforcement, which has been described as the major component of self-control. For example, Goldiamond (1976) states that this term is also a misnomer just like self-control. What seems to be at issue is that the definition of self-reinforcement generally refers to thosearrangements in which the subject delivers to himself a consequence, contingent on his behavior. Goldiamond voices his concern that the agent who defines whether or not the response required for reinforcement has been met may not do so correctly. In other words with other forms of reinforcement an outside agent determines whether a requirement has been met and if so, then delivers the reinforcement. With self-reinforcement you don't have that opportunity. In an attempt to bypass some of these controversial issues the term self-reinforcement will be replaced with the term self-delivery of rewards.

Summary

In the review of the behavioral medicine literature two major deficiencies were found. First, despite the fact that adherence to a medical regimen has been labelled the single greatest problem in providing effect-

ive medical care and that the problem is of severe proportions (Pomerleau, 1979), there has been sparse empirical research of the problem. Second, given that self-control procedures have been used effectively in other medical areas such as obesity and that it (self-control) has been recommended as one of the future directions in improving compliance (Pomerleau, 1979), the presence of only one attempt at self-control techniques with patient compliance (Epstein & Masek, 1978) reveals an even more drastic need for further research.

Considering that in the last 20 years there has been a shift in the types of diseases studied, from infectious to chronic (Epstein & LaPorte, 1978), the need for further research with chronic diseases is imperative, especially since of the behavioral medicine research conducted, only a few studies have looked at chronic diseases such as hypertension (e.g., Sackett, Haynes, Gibson, Hackett, Taylor, Roberts, & Johnson, 1975), asthma (e.g., Renne & Creer, 1976), and diabetes (e.g., Lowe & Lutzker, 1979). Also, the only self-control study conducted (i.e., Epstein & Masek, 1978), examined Vitamin C consumption.

There is serious concern about the results of drug research studies because of the problem of patient noncompliance. Some researchers suggest that there is evidence that the results of many published trials of drug efficacy may require reanalysis because medication compliance was not reliably assessed (e.g., Blackwell, 1972; Soutter & Kennedy, 1974). Therefore, it seems practical to get involved in a drug study to determine the levels of medication compliance in patients. If some patients are then identified as noncompliers, they must be placed in a treatment program to increase their compliance behavior if their results

are to contribute meaningfully to an assessment of the drug effects.

In conclusion, the purposes of the present research will be to: (1) focus on a drug research study involving chronic disorder subjects which have not been examined previously (i.e., arthritics), (2) take data on the medication compliance behavior of subjects in a drug study, (3) identify subjects in this drug study who are noncompliant with the medication regimen, and (4) introduce a behavioral self-control treatment package to these subjects to determine its effectiveness.

Method

Subjects

A group of 21 arthritic patients who had been selected by the Head of Rheumatology at the Rehabilitation Centre, Health Sciences Centre, Winnipeg, Manitoba, to become involved in a new drug research study, served as the subject pool for this self-control study. These patients were selected because their current medications were not adequately controlling their arthritis. All 21 patients fulfilled the criteria of active rheumatoid arthritis. As well they did not meet any of the criteria for exclusion. For example, patients could not have any other serious health problems, or be receiving specific medications such as non-steroidal anti-inflammatory agents which could not be discontinued. (See Appendix C for a detailed list of these criteria).

All 21 patients were baselined for a minimum of five weeks and then four of the worst compliers were selected as subjects for the self-control study. Subject 1 was a 48-year-old man who had a 12 year history of rheumatoid arthritis. Mr. T was working as a sheet metal worker but had been forced to gradually reduce his work output due to the progressiveness of his disease. Subject 2 was a 69-year-old man who had a 9 year history of rheumatoid arthritis. Mr. B was retired. Mr. B was subsequently dropped from the study after 8 weeks due to the occurrence of health complications unrelated to the medications. Subject 3 was a 43-year-old woman who had a 10 year history of rheumatoid arthritis. Ms. S was working as a secretary. Subject 4 was a 73-year-old woman who had a 6 year history of rheumatoid arthritis. Ms. L was retired. Ms. L was of special interest since she had been described by some of the rheumatology doctors as having a hisory of noncompliance with several occasions of

confusion over medical instructions.

Setting

The study was conducted in the Out Patient Department in the Rehabilitation Centre at the Health Sciences Centre. The sessions were conducted in the examination room in the Out Patient Department. The room measured 2m by 3m and was equipped with an examination table, a desk, and two chairs.

Apparatus

The watch used in this study was a Remex Quartz 9 Function LCD Alarm Watch. The watch had a variety of functions but the 24hr alarm aystem was of major importance.

Medications

Medications used were prepared by the Medical Divison of Pfizer Canada Incorporated in Quebec, Canada. Four types of medications were used. Two types were pills which were identical in size, shape, and color and contained either 650 mg of acetylsalicyclic acid (ASA) or were placebos. This medication was to be taken four times a day and depending on prescribed dosage would total 5-8 pills a day. The other two types of medication were capsules which were also identical in size, shape, and color to each other and contained either 10 mg of Piroxicam or were placebos. This medication was to be taken only once a day in the morning and depending on prescribed dosage would total 1 or 2 pills a day.

Measurement of Compliance

Compliance was assessed in four ways. Three of the measures were direct assessments of compliance while the fourth measure looked at the effects of compliance behavior upon related physiological measures. The first method of measuring compliance was the pill count method. The med-

cations from Pfizer of ASA and Piroxicam were pre-packaged in weekly allotments. One pill vial contained 64 ASA pills while the second pill vial contained 16 Piroxicam pills. (These amounts were based on maximum dosages of each medication/day for 8 days). Due to the large number of ASA pills in each vial, and consequently the large number that would be left over, only the number of Piroxicam pills were altered by adding a random number of extra pills chosen from a random numbers table. The number of extra pills ranged from 0-9.

The second method of measuring compliance was the measurement of blood serum levels. Specifically, ASA has a characteristic therapeutic concentration level of salicylate in the blood (i.e., 20-30 mg/dl, 1-4 hrs. after last dose) while Piroxicam has a characterisitic therapeutic concentration level of piroxicam in the blood (i.e., $\geq$6mg/dl, 1-4 hrs. after last dose. These measures were taken an average of once every two weeks for each subject.

The third method of measuring compliance was studying the effects of compliance behavior and consequently proper consumption of the pills, upon specific physiological measures of arthritis. A physiotherapist, who was blind to the specific medications each subject was on, did a total of seven physiological assessments for the duration of the self-control study. The physiotherapist took measures on: (1) number of joints tender on motion; (2) number of joints swollen; (3) an average measure of grip strength of both hands; (4) patient's comparison of their pain and physical activities to their last visit as being either Better, Same, or Worse; and (5) patient's assessment of their pain level for the last 24 hours as ranging from none to very severe on a 6 point scale. These assessments were then compared to the compliance levels for all subjects.

The previous three measures were taken throughout the entire study, however a fourth compliance measure, self-monitoring, was only used during the treatment and follow-up phases. The reliability of subjects self-monitoring, which was one of the complonents of the self-control package, was assessed via comparison with pill counts.

Sel-Control Package

At the end of each subject's baseline phase she/he was introduced to the self-control package. The instructions on the use of the package required approximately one hour for each subject. When the package was introduced each subject was told that Pfizer and the Head of Rheumatology were interested in studying the effects of a variety of procedures in helping people to remember to take their pills. They were told the package was to be given to as many patients as possible. At the end of each week any problems the subjects had with the package were discussed.

The self-control package had four components. Two of the components were to act as cueing devices. The first one was the alarm watch. Each subject was instructed in the use of the watch and told to reset the alarm for each successive medication period. The subjects were required to set their watches a maximum of four times a day.

The second cueing device was the use of a set of instructions. The instructions were printed on standard 7.5mm x 12.5mm white index cards and had three components: (1) "Did you take your pill", (2) "Did you reset your watch", and (3) "Did you reinforce yourself". A maximum of four cue cards were given to each subject. The subject was asked to post two in the home (e.g., one on the bathroom mirror and one on the fridge door), and to place one in her/his purse or wallet. If the subject worked then she/he

was also asked to post the fourth cue card at work (e.g., on their desk).

The third component of the self-control package was self-monitoring. Each week subjects received one vial containing 64 ASA pills and the other vial containing 16 Piroxicam pills plus a specified number of extra pills. The specific number of extra pills was chosen from a random numbers table. Subjetcs received a small pocket sixe data sheet on which one week of compliance data was collected. The data sheet was explained to each subject and she/he was asked whether they took their required amount of medication for each daily time period or not.

The final component of the self-control package was self-delivery of rewards. Subjects first filled out the Reinforcement Survey Schedule (Cautela & Kastenbaum, 1967) and then based on their answers the experimenter helped them to chose one suitable reward. (e.g., working on a stamp collection, relaxing and reading a book). Based on the self-monitoring data, rewards at the end of each day was dependent upon 100% compliance to the medication regimen.

Procedure

Baseline data were collected on all 21 subjects in the drug study. The types of medication they received (i.e., ASA or Piroxicam) was decided by the drug code schedule developed by Pfizer. After a minimum of five weeks of baseline the four worst compliers (based on pill count data) were selected as subjects for the self-control study. Data continued to be collected on the subjects who were not selected for the self-control study. Due to the infeasibility of assessing all arthritic patients on the same day their starting times extended over a 4 week period. The self-control package was introduced to the noncompliant subjects in a multiple baseline across

subjects design which was staggered over time. The baseline and treatment phases for each subject were conducted during the first 12 weeks of the study (except Subject #1 who had 14 weeks to give two more weeks of treatment data). Following this period all subjects were told what medications they were on and based on the decision of the Head of Rheumatology that were functioning well on their active medication (i.e., Piroxicam for Subject #1, and ASA only for Subjects #3 and #4 since #2 had been discontinued earlier due to other medical difficulties) they continued their current medication for a minimum of one more month. This second phase of the drug study constituted the start of the follow-up phase in the self-control study. Data continued to be collected during this follow-up phase but the subjects were seen only once during this time period. The subjects were asked to continue with their self-control package as before.

Finally, at the end of the follow-up phase all participating individuals (i.e., Head of Rheumatology, physiotherapist, and Subjects #1, #3, and #4) completed a social validation questionnaire. The questionnaire asked for their comments and opinions about the effectiveness of the self-control package.

Results

The interobserver reliability was 96% for the weekly pill allotments (i.e., pre-packaged allotments) and 100% for the extra pills returned each week by all subjects. These interobserver measures were calculated as to the ratio of the number of agreements between the author and the physiotherapist to the number of agreements plus disagreements multiplied by 100.

Figure 1 shows the medical compliance data for each subject individ-

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Insert Figure 1 about here

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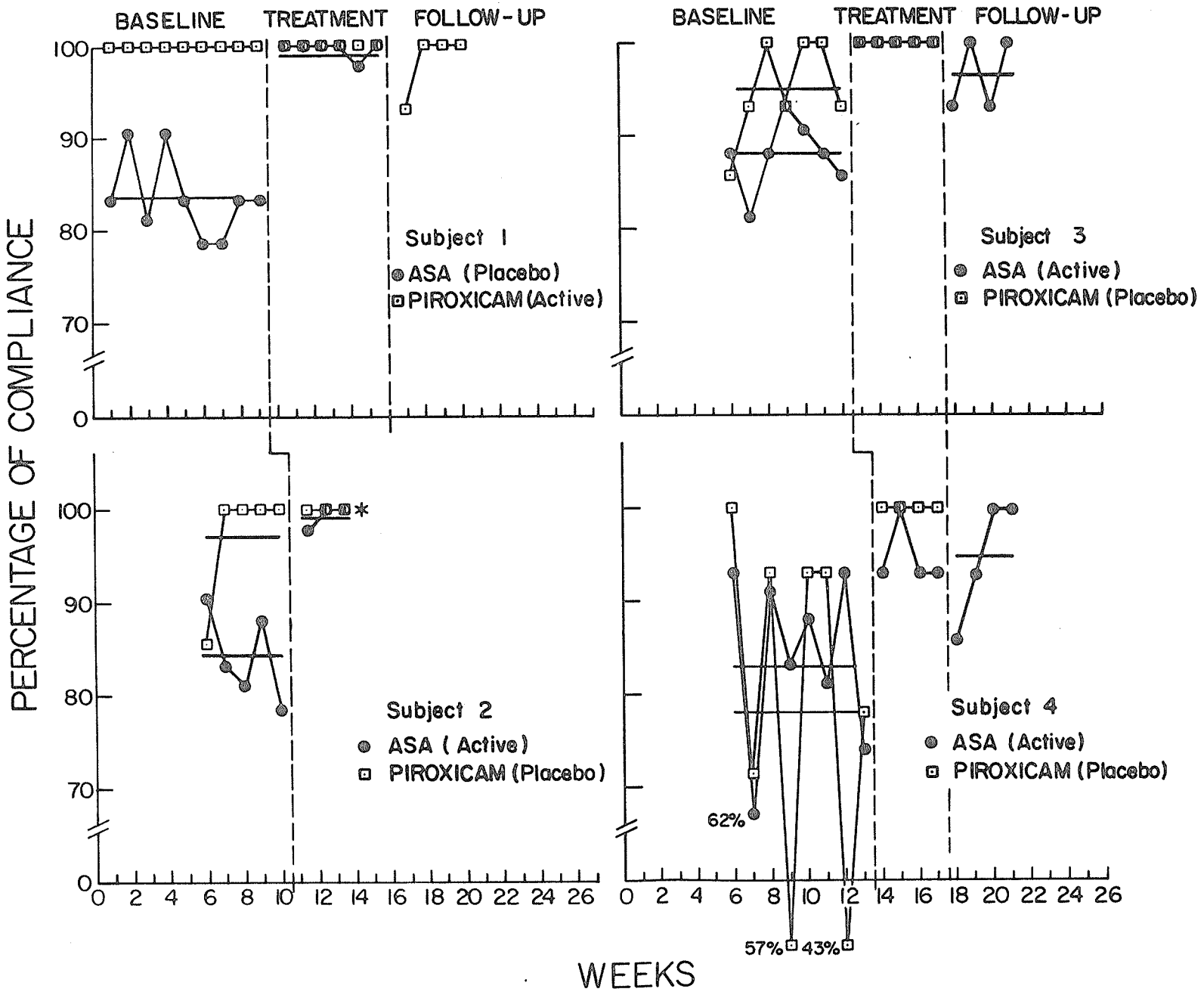
ually. Due to the constraints of an already established drug study, compliance data were taken on a weekly basis to coincide with the scheduled weekly visits of the patients. The commencement of data collection on subjects was determined by their assignment date to the drug study and thus the appearance of missing data for Subjects 2-4 prior to baseline reflects their different starting times and not missing data. Furthermore, timing of the introduction of the self-control package was also partially determined by the scheduling of the drug study and the availability of subjects.

During baseline, Subject 1 was 100% compliant with Piroxicam while he averaged 84% compliance with ASA. During treatment compliance of Piroxicam remained at 100% while compliance of ASA rose to an average of 99%.

During baseline, Subject 2 averaged 97% compliance with Piroxicam while he averaged 84% compliance with ASA. During treatment compliance

Figure 1. The percentage of compliance for Subjects 1-4 for both ASA and Piroxicam. Note the distinction of active and placebo medications for each subject. The arterisk (*) denotes the termination of Subject 2 due to health difficulties.
The average number of Piroxicam/day = 2, 14/week.
The average number of ASA/day = 6, 42/week.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TREATMENT
FOLLOW-UP
PERCENTAGE OF COMPLIANCE
100
90
80
70
0
Subject 1
ASA (Placebo)
PIROXICAM (Active)
Subject 3
ASA (Active)
PIROXICAM (Placebo)
Subject 2
ASA (Active)
PIROXICAM (Placebo)
Subject 4
ASA (Active)
PIROXICAM (Placebo)
62%
57%
43%
0 2 4 6 8 10 12 14 16 18 20 22 24 26
WEEKS

of Piroxicam rose immediately to 100% while he averaged 98% compliance with ASA. Subject 2 was discontinued after Week 13 due to medical difficulties unrelated to the drug study (i.e., pneumonia). Subject 2 did recover but too late to continue in the study.

During baseline, Subject 3 averaged 95% compliance with Piroxicam while she averaged 88% compliance with ASA. During tretament compliance rates of both Piroxicam and ASA rose immediately to 100% and were maintained.

During baseline, Subject 4 averaged 78% compliance with Piroxicam while she averaged 83% compliance with ASA. During tretament compliance rose immediately to 100% for Piroxicam while she averaged 95% compliance with ASA.

During follow-up, where all three remaining subjetcs continued with the self-control package, but were only seen at the end of one month, the subjects continued with near-perfect compliance levels. The pill count data was again taken from weekly pre-packaged allotments. Subject 1 averaged 99% compliance with Piroxicam while Subject 3 averaged 97% compliance with ASA and Subject 4 averaged 95% compliance with ASA.

Table 1 indicates the respective Piroxicam or salicylate levels in

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Insert Table 1 about here

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the blood for each subject. Subject 1 (the only one on Piroxicam) shows a small degree of variability during baseline and treatment around the optimal therapeutic level of 6mg/dl or greater in the blood. There appears to be no clear distinction between the two experimental phases. Subject 2 shows

Table 1

Levels of Piroxicam and Salicylates in Blood Samples

Subject 1

Week	Piroxicam Level
1	5.84
2	4.65
3	7.82
4	6.16
8	6.31
Treatment	
12	6.27

Subject 2

Week	Salicylates Level
7	10.2
9	7.1
10	16.7
Treatment	
12	17.8

Subject 3

Week	Salicylates Level
8	28.3
9	28.7
10	27.0
Treatment	
13	26.3
15	21.8
16	33.7
17	23.1

Subject 4

Week	Salicylates Level
8	31.7
9	28.7
10	15.5
Treatment	
14	18.7
16	19.1
17	22.2

Respective levels of Piroxicam ($\geq$ 6 mg/dl, 1-4 hrs after last dose) and salicylates (20-30 mg/dl, 1-4 hrs after last dose) in blood samples for all subjects during baseline and treatment. (Note: Follow-up data could not be obtained due to a hospital strike.)

some slight improvement in salicylate levels during treatment with the highest level (i.e., 17.8) being attained during treatment, although the last salicylate measure during baseline had shown a comparably high level (i.e., 16.7). Subject 3 shows considerable variability in her salicylate levels during both baseline and treatment, although once again the highest level attained (i.e., 33.7) was during treatment. Subject 4 shows the clearest improvement in salicylate levels as compared to the other subjects. During baseline her salicylate levels steadily decreased while during treatment the levels steadily increased. Although Subject 4 had two of the highest salicylate levels during baseline (i.e., 31.7 and 28.7) these can be attributed to the fact that the subject had not discontinued her other medications as requested, which contained salicylates, during the first few weeks of the study. This was discovered in a conversation with the subject during one of the weekly sessions.

The interobserver reliability results between pill counts and self-monitoring for each subject was 97% representing a high degree of correspondence between the two measures. This 97% score was based on the ratio of the number of agreements between the pill count data and the self-monitoring data to the number of agreements plus disagreements multiplied by 100. This high level documents the validity of self-monitoring data in the present study, which is in strong contrast to much of the self-monitoring data (e.g., O'Leary & Dubey, 1979). Since the self-monitoring data are repetitious of the pill count data, the results have been included in Table 1 of Appendix D.

The results for joint swelling, pain levels, etc. were very unclear. Since half of the measures relied on patients' subjective assessments,

while the other half relied on the physiotherapist's subjective assessments, there is some question as to the objectivity and reliability of these measures. However, the results have been included in Table 2 of Appendix D for examination by the interested reader.

In terms of the compliance data for the 26 subjects not in the self-control study, they missed a total of 202 Piroxicam pills and 759 ASA pills over a period ranging from 3 to 12 weeks. This time period varied because some subjects dropped out of the study when they felt their arthritic condition was not improving or was in fact getting worse. The mean number of Piroxicam pills missed was 7.5 (range 0-23 pills) while for ASA the mean number of pills missed was 28.1 (range 3-78 pills). The mean number of pills missed per week was .94 (range 0-2.8 pills) for Piroxicam and 4.55 (range .54-15.5) for ASA. The subject who scored 15.5 dropped out of the study after two weeks and thus could not be utilized in the self-control research. For the four subjects in the self-control study, the mean number of pills missed per week was 1.16 (range 0-3.0) for Piroxicam and 6.6 (range 5.1-7.1) for ASA. These four subjects were, of course, selected on the basis of their lower compliance rates.

Discussion

Except for the study by Epstein and Masek (1978) which employed self-monitoring, no other studies appear to have investigated medical compliance behaviors using self-control procedures, particularly a self-control treatment package. The results for pill counts in the present study, displayed in Figure 1, offer excellent examples of the effectiveness of the behavioral self-control package. All subjects increased their compliance behavior immediately after introduction of the package and maintained these high levels for the duration of the treatment and follow-up phases. Based on each subject's data, during treatment there were only 5 ASA pills and 0 Piroxicam pills missed in a total of 18 weeks of treatment, and, during follow-up only 5 ASA pills and one Piroxicam pill were missed in a total of 12 weeks. In comparison, during baseline the number of missed ASA pills was 187 while the number of missed Piroxicam pills was 31 over a total of 29 weeks.

Since pill counts were one of the major measures of compliance in the present study, reliability checks were taken on these medications. Twenty packages of pills (or approximately 30% of the medications dispensed to the four subjects during the study) were counted to determine the accuracy of the pre-packaged pill counts. Of these 20 packages counted seven had one extra ASA pill while one had an extra Piroxicam pill. All of the remaining packages were accurate. Because of this discrepancy in the accuracy of the number of pills in the weekly packages, it is possible that some of those five ASA pills missed during treatment were due to having an incorrect count of pills in the package. The packages of medications dispensed during follow-up were carefully counted prior to

dispensing, and therefore, the five ASA pills and the one Piroxicam pill missed accurately reflect compliance behavior.

Returning to the treatment data, Subject 1 who missed one ASA pill during treatment, reported that he had missed this pill because when his alarm watch buzzed he was in his car driving outside the city with no water to wash down the pill. He reported that he was unable to take these pills without a liquid of some kind. Therefore, for all subjects, that leaves the four remaining ASA pills missed during treatment. If an adjustment were made based on the fact that seven of the 20 packages (or 35% of the packages checked) had extra pills, this would leave 65% or 2.6 pills during treatment which presumably were not taken, an even more optimistic index of the success of the self-control program.

The identification of Subject 4 by the Rheumatology doctors as being someone who had difficulty remembering and following instructions appears to have been accurate. Subject 4 was clearly the most noncompliant subject and yet the self-control package was equally effective for her as for the other subjects. Therefore, due to this patient's high degree of noncompliance, she offered the self-control package a stringent test of its general effectiveness.

The data from Figure 1 also clearly support observations of various researchers that increased complexity of medical regimens dramatically reduces levels of medical compliance (e.g., Haynes, 1976; Pomerleau, 1979). One of the suggested positive factors with the new drug, Piroxicam, as compared to ASA was the simplicity of its regimen (i.e., a maximum of two or three pills versus six to eight pills). The ASA has to be taken four times a day with each medication amount varying from one to two pills

while Piroxicam usually has to be taken only once in the morning in a dosage of two pills. However, regardless of the different degrees of complexity of these two medications the self-control package proved to be equally effective. Therefore, the power of this particular self-control package seems convincingly demonstrated under stringent client and regimen conditions.

In reviews of the medical compliance literature, estimates of the degree of noncompliance have ranged from 20% to 80% (e.g., Marston, 1970). There is, however, a problem in comparing studies for their level of non-compliance because of the different definitions of noncompliance. For example, Morrow and Rabin (1966) classified patients as being noncompliant if 50% or less of their urine specimens were positive while Wynn-Williams and Arris (1958) classified patients as being noncompliant on the basis of one negative blood test result. For this particular study, the average number of pills for each medication to be taken in a week (i.e., 14 Piroxi-cam and 42 ASA) was multiplied by the number of weeks each patient was in the drug study. This yielded an estimate of the total number of pills to be taken by each patient. Then, for each patient the percentage of non-compliance was calculated as the ratio of the number of missed pills to the total number of pills to be taken multiplied by 100. This index was calculated for all 30 patients in the study and then averaged. The mean values were 7.5% noncompliance with Piroxicam and 11.2% noncompliance with ASA. There are at least two explanations for these low rates of noncompliance. Firstly, the medical compliance literature is rather deficient of studies with arthritic condition. Arthritis appears to be a chronic disorder which has a relatively good correlation between failure

to take medications and degree of discomfort, as compared, for example, to hypertension which does not have nearly the same degree of correlation. In other words, if an arthritic person fails to take his medication and relatively soon after has discomfort, he/she would be more likely to take the medication. Therefore the possibility of better stimulus control between taking medications and less or no discomfort appears a likely explanation for increased compliance. Secondly, because these patients were in a new drug study, and had been picked because their current medications were not adequately controlling their disease, they conceivably would be more concerned about taking their medications than someone taking Vitamin C (for example, Epstein & Masek, 1978). It would be interesting to observe other arthritic populations to determine if they exhibit similarly high rates of compliance.

A major concern of medical compliance research has been the validity of measures of compliance (e.g., Marston, 1970; Russo et al., 1980). The use of multiple measures in the present study, particularly the combination of pill counts, self-monitoring, and blood serum levels, appears to have provided a relatively comprehensive and convincing assessment of compliance with the prescribed regimens, at least in the context of a drug research study involving arthritic patients. The more "subjective" measures, ratings of joint swelling, pain levels, etc. were significantly less successful in accord with Russo et al.'s (1980) concern about the reliability of the measures of patients' symptoms.

The especially close correspondence between self-monitoring and pill count data, suggesting high validity for self-monitoring, is in direct contrast to the usual finding of questionable validity for self-monitoring

(e.g., O'Leary & Dubey, 1979). The particular conditions of the present research; a relatively debilitating illness, the research study control, and a self-control package, may all have contributed to improved accuracy of self-monitoring. It remains for future research to isolate the most relevant components.

The validity of human drug research is directly related to the degree of compliance of the patients taking medication. Serious criticism has been leveled at drug studies lacking compliance measures for patients (e.g., Blackwell, 1972; Soutter & Kennedy, 1974). While the percentage of noncompliance rates of the present study were relatively low on the average (7.5%-11.2%), there was considerable variability in noncompliance (range 0-36% for Piroxicam and 1-37% for ASA). Irrespective, logically, the best comparative clinical evaluation of drugs can only be conducted under optimal conditions of patient compliance, those achieved by the present behavioral self-control package.

At the conclusion of the study, the three remaining subjects were administered a social validation questionnaire which asked for their comments and opinions about the self-control package as a whole and about individual components (see Appendix E). The data collected from this questionnaire provide further support for the results shown in Figure 1. First, Subject 1 who had perfect compliance with his active medication, Piroxicam, and very poor compliance with his placebo medication, ASA, during baseline did not know which of the two medications was active and which was not. Therefore, his poor compliance with the placebo pill does not appear to reflect any knowledge on his part about the types of medications he was taking. Secondly, Subjects 1 and 3 assumed that pill counts were being done as

a matter of course for the drug study, yet this did not appear to influence their compliance rates. In other words, even with some suspicion that their pill counts were being monitored, these two subjects continued to exhibit poor compliance during baseline. Subject 4, meanwhile, had no suspicion that her pill counts were being monitored. Information gathered during the social validation questionnaire on the individual components of the self-control package revealed the following preferences. Subjects 1 and 3 thought the alarm watch was very useful and similarly Subject 3 thought cue cards in conjunction with the alarm watch were extremely effective for her. In contrast, Subject 4 found the watch difficult to operate and data sheets to be to her most effective component. However, Subjects 1 and 3 both stated they thought the data sheets were more an inconvenience than an asset.

In summary, the results in Figure 1 show the self-control package to be highly effective with all subjects, and the social validation questionnaire data document the general value of the stimulus control provided by the alarm watch. The importance of developing stimulus control for medical compliance has been advocated by many researchers (e.g., McKenney, 1981). As well, the alarm watch and the cue cards were identified by Subjects 1 and 3 as fostering family involvement. The development of a cooperative and supportive social environment has been advocated as a strong variable in developing and maintaining compliant behavior (e.g., Haynes, 1976; Pomerleau, 1979). The alarm watch, however, was not totally successful with all subjects because Subject 4 had some difficulty in operating the watch and therefore tended to rely more on the self-monitoring data sheets. One of the values of a treatment package

is that it provides a variety of components which may be differentially useful to different subjects.

In terms of future research, several recommendations can be made. Based on the success of this self-control package, further direct replication with arthritic patients, as well as systematic replications with various other chronic disorders (e.g., diabetes, glaucoma) is warranted. The individual components of the self-control package deserve independent evaluation, especially in light of the variation in subjects' estimations of the effectiveness of each component . However, given the degree of problem for the subjects in operating the alarm watch, especially Subject 4, a more manageable apparatus needs to be used. The apparatus must be pocket-sized and easily operated. To assist generalization to the natural environment, the apparatus should approximate something that normally appears in the natural environment (i.e., like the watch).

Other recommendations for research include the nature of the medications themselves. Considering Subject 1's difficulty in taking his pills when no liquids were available, perhaps the provision of chewable pills would alleviate this problem. Furthermore, results from the present study clearly indicate the difficulties with compliance to complex medical regimens. If medication can be developed with longer half-lives, this would greatly reduce the frequency of pill-taking, and therefore likely improve compliance.

In conclusion, the total pattern of the present results offers convincing support for the view that behavioral principles are effective in bringing about a positive change in health-related behaviors. These treatment package results represent another source of validation for Azrin's (1977)

total package approach. Azrin's argument is that the first responsibility of the therapist is to change the behaviors of clients in a positive direction as quickly as possible. He suggests combining a variety of components which you think will be effective, into a package which strives for maximal behavior change.

The positive and dramatic effects of the self-control package also validate the opinions of other researchers as to the probable effectiveness of self-control procedures in the behavioral medicine field (e.g., Pomerleau, 1979). The practicality of the self-control package and its immediate effect on raising levels of compliance should prove a tremendous asset to the medical community both in treatment of patients and in research on the comparative effectiveness of medications.

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Appendix A

Review of Behavioral Medicine

The field and the term behavioral medicine are quite new, with the first use of the term being by Birkin in 1973 (Epstein, Katz, & Zlutnick, 1979). An indication of the remarkable growth of the behavioral medicine field within the last two years is descibed in a recent article, "... the formation of a special branch of the National Heart, Lung and Blood Institute and of a study section for training in the National Institute of Health, the convocation of several clinical research centers at major medical schools, the creation of a special interest group of the Association for Advancement of Behavior Therapy, the establishment of two national research societies, and the emergence of a spate of published and to-be-published articles and books, all with the formal designation of behavioral medicine" (Pomerleau, 1979, p.654).

To avoid any confusion, the term "behavioral medicine" used in this review will be defined as: (a) the clinical use of techniques derived from the experimental analysis of behavior-behavior therapy and behavior modification - for the evaluation, prevention, management, or treatment of physicial disease or physiological dysfunction; and (b) the conduct of research contributing to the functional analysis and understanding of behaviors associated with medical disorders and problems in health care (Pomerleau & Brady, 1979).

Within the area of clinical behavioral medicine, Pomerleau (1979) has identified four prinicipal lines of development: (1) intervention to modify an overt behavior or physiological response that in itself constitutes a problem; (2) intervention to modify behavior of health care providers to improve the delivery of service; (3) intervention to

modify adherence to prescribed treatment; and (4) intervention to modify behaviors or responses that contribute risk factors for disease. This review will focus on the adherence problem and will evaluate studies which have investigated this topic.

Patient Compliance

According to Pomerleau (1979): "There has been a growing awareness that failure of patients to adhere to a prescribed medical regimen is probably the single greatest problem in providing effective medical care." This concern over lack of compliance on the part of patients seems to be an ideal area for behavioral intervention. Adherence is after all fundamentally a behavioral problem, since it involves getting a patient to take medications in proper dosage and on schedule, or getting a patient to follow a prescribed diet. For example, Zifferblat (1975) advocated "solutions to medical compliance can come from applied behavioral analysis of medication-taking behaviors".

In terms of the magnitude of the compliance problem, current estimates are that between 20% and 80% of patients do not follow their regimens, with an average of only 50% of patients on long term medication or diets compliant (Pomerleau, 1979). As might be expected, due to the magnitude of this problem, considerable attention has been devoted to identifying factors that control compliance. Marston (1970) developed an extensive review of compliance studies prior to the 1970's.

Early Research (Pre-1970's)

In her introduction Marston explained that due to increasingly effective drug therapy programs and the development of the general hospital as an acute care center, more people than ever are being given responsibility

for their own care in their own home. As a result of this shift in the focus of medical care, the medical profession is becoming increasingly concerned about the compliance of patients. Based on this concern, Marston analyzed compliance studies and attempted to compare similar studies. This is where she encountered her first difficulty. Researchers have varied greatly in their techniques to measure compliant behavior. However, she did uncover three fairly common techniques: (1) drug excretion, (2) pill counts, and (3) more than one technique (i.e., patient self-reports combined with one of the other two techniques). In the first part of her review she used these three categories to separate the studies.

Drug Excretion Tests

The this technique the patient's medication contains a particular chemical which can be detected later in the patient's blood specimen or in the more common urine sample. On the surface this test appears very objective, but Marston discovered a great deal of variability in the definitions. She stated: "Even with as objective a measure as the presence of a drug, or marker, in the patient's urine, problems arise when attempting to compare compliance rates. Operational definitions of compliance vary from one study to another...some using the test result of one urine sample collected at the time of the patient's visit...others have based their estimates on repeated measures".

A second problem that Marston encountered, was that researchers ascribed compliance to varying proportions of positive or negative test results. Morrow and Rabin (1966) classified patients as being noncompliant if 50% or less of their urine specimens were positive. This certainly seems a much too liberal classification system. On the opposite extreme, Marston reported that the researchers Wynn-Williams and Arris (1958)

classified a patient as being noncompliant on the basis of only one negative test result.

Pill Counts

Some investigators have used pill counts, (i.e., varying the number of extra pills), or the return of the patient for replenishment of their drug supply at the appropriate time, as an indication of patient compliance (e.g., Jenkins, 1954; Lipman, Richels, Uhlenhith, Park, & Fuher, 1965; Roth, Caron, & Hsi, 1970). The obvious reliability problem with this method is that failure to return any leftover pills does not necessarily mean the patient has taken the remaining prescribed medication (Marston, 1970).

The lack of agreement on definitions for compliance is also evident in the pill count studies. For example, Lipman et al. (1965) gave neurotic oupatients an excess of tablets, along with instructions to return any unused tablets at their next visit. Patients were considered to have "deviated", if their pill counts revealed that they had taken less than an average of six tablets daily, eight daily having been the prescribed dosage. In this particular study a 25% deviation constituted noncompliance. Using this criterion, Lipman et al. (1965) concluded that 45.7% of patients deviated from their physician's medication recommendations. In another study, Jenkins (1954) found that of 22 patients, four took all or nearly all their drugs, 12 took less than 60%, four took about 50%, and two took practically none of their drugs. Marston comments that somehow from these data Jenkins concluded that his patients were about 50% faithful in adhering to their medication. This practice of affixing specific percentage values to nonspecific data is inaccurate and misleading. Therefore, eventhough the percentages of these two studies are similar

they are not comparable since the data on which the noncompliance estimates were based, differ.

More Than One Technique

A few investigators have concerned themselves with comparing medical compliance rates using more than one technique. Patient reporting is probably the easiest method for measuring compliance and has been used in conjunction with results of excretion tests and pill counts. When Gordis, Markowitz, and Lilienfeld (1969) compared patient reporting with results of urine tests, the noncompliance rates based on patients reports ranged from 9% to 15% but excretion tests revealed rates of non-compliance from 22% to 35%.

Comparison of patient reports with pill counts have also shown similar discrepancies. Park and Lipman (1964) compared patient reports with pill counts for a group of neurotically depressed out-patients. Bi-weekly pill counts revealed a 51% deviation from the prescribed dosage, whereas patient reports revealed only 15% deviation. However, others have found self-reports, when compared with other methods of assessment, to yield accurate results (e.g., Feinstein, Wood, Epstein, Taranta, Simpson, & Tursky, 1959; Francis, Korsch, & Morris, 1969).

More recently, Roth et al. (1970) compared self-reports, serum tracer, and bottle count. Their results showed that the tracer technique was the only reliable procedure with pill counts being slightly better than self-reports which were very unreliable.

Direct Observation

A group of investigators from the University of North Carolina have gone so far as to directly observe diabetic patients in their home (e.g., Watkins, Robert, Coyle, & Williams, 1966; Watkins, Martin, Hogan, &

Anderson, 1967). The results showed that 80% of the patients failed to administer insulin in an acceptable manner and about 50% used the urine test incorrectly.

Behavioral Engineering

Azrin and Powell (1969) utilized a portable mechanical operant device which indicated the time to take medication by sounding a tone. In order to terminate the tone a dial on the device had to be turned which then caused a pill to be dispensed.

Demographic, Illness, and Social-Psychological Variables

The second part of Marston's (1970) review summarized studies which had investigated the relationship of demographic, illness, and social-psychological variables to compliance behavior. She concluded that: "Demographic variables such as age, sex, socio-economic status, education, religion, marital status, and race, when examined apart from other variables have rarely been predictive of compliance with medical recommendations" (p. 317). In terms of illness and social-psychological variables, Marston stated: "It is unclear whether actual severity of illness is related to compliance, although severity, as perceived by the patient, probably results in increased compliance...the recent use of various personality tests to predict compliance has also been disappointing" (Marston, 1970, p. 320).

The review by Marston demonstrated that the studies on compliance conducted prior to 1970 were concerned primarily with ways to objectively measure compliance and with the relationship between compliance and numerous variables (e.g., demographic, illness, and social-psychological). In other words the early research was more descriptive than explanatory. As two other authors put it: "The common aim was to identify groups of

nonadherers, often with the hope that identification would solve the problem. For that reason, much of the research was essentially atheoretical, and many variegated factors were investigated whose reason for inclusion was at best, only implied" (Kirscht & Rosenstock, 1979, p. 196). Research studies which did attempt to modify compliance behavior did not start appearing until recently.

Recent Research (Post-1970)

Haynes (1973) investigation appears to be one of the first attempts to modify patients' compliance behavior. He conducted a community-based program for chronic alcholics. The treatment group consisted of alcholics who had a long history of arrests for public intoxication. This group was given the choice of "volunteering" for an Antabuse program or being sent to jail for 90 days. The 138 subjects who voluntered were required to take their medication (Antabuse) twice a week at a municipal court. Two missed appointments resulted in a response-cost procedure in which the subject was sent to jail for 90 days. The results for these 138 subjects after one year showed over half were still in the program. This was a sharp improvement over traditional alcoholism programs.

Another program which looked at compliance to Antabuse in alcoholics was conducted by Bigelow, Strickler, Leibson, and Griffiths (1976). These authors used a money-deposit contract. Each missed appointment resulted in a forfeit of $5. Results showed patients to be abstinent over 95% of the treatment period.

Some researchers have suggested that two of the factors creating patient compliance problems are lack of education of the patient regarding his ailment and the degree of accessibility to the medication. Therefore,

Sacket, Haynes, Gibson, Hackett, Roberts, and Johnson (1975) worked with a group of steelworkers who were using anti-hypertensive medications to study these two factors: (1) treatment convenience, and (2) patient knowledge. Treatment convenience was studied by comparing the subjects who had to go their doctor's office versus those subjects who could get their medication on the job. Patient knowledge was studied by comparing those subjects receiving a booklet on hypertension, some comments on the need for compliance to medical regimens, and some tips on how to remember to take their pills versus those patients who did not receive any of this information. The results showed similar levels of compliance acress all groups with a range of 50% to 56%. Thus, neither access to treatment nor mastery of hypertension information affected compliance rates. The effectiveness of instructions alone (as opposed to when they are combined with reinforcement contingencies) in generating compliance is a well established behavioral phenomenon (e.g., O'Leary & Dubey, 1979).

Interestingly, a few years ago, it was estimated that only one of eight persons with essential hypertension (high blood pressure of unknown causes) had achieved blood pressure control; yet this condition is regarded as the number one risk factor for coronary heart disease and stroke. It has been suggested that a large portion of this lack of blood pressure control is due to difficulties in adherence (Kirscht & Rosenstock, 1979).

Three studies have looked at the effects of reinforcing compliance behavior. Miller, Hersen, and Eisler (1974) analyzed the effects of instructions, contracts, and reinforcement upon the compliance behavior of 40 chronic alcoholics. Results indicated that while instructions and behavioral contracts had limited influence on drinking, both groups receiving reinforcement for compliance significantly decreased their

operant drinking.

The remaining two studies used token reinforcement procedures. Renne and Creer (1976) used instructions, prompting, and token reinforcement to increase the proper use of an intermittent positive pressure (IPPB) apparatus with four asthmatic children. Despite the noncompliance history of these four subjects, the reinforcement procedure was found to be very effective in increasing IPPB behaviors.

Magrab and Papadopoulou (1977) examined the effects of token reinforcement upon dietary compliance of four children on hemodialysis. Three measures were scored: (1) weight, (2) blood, urine, and nitrogen (BUN), and (3) potassium levels in the blood. The children received a certain number of points for maintaining acceptable levels on each of these measures. In an ABA design the results showed that the reinforcement procedures were very effective in controlling these measures.

Recently, Epstein and Masek (1978) were interested in developing a reliable, easily manipulated procedure for measurement and modification of compliance behavior. With a college population they compared four groups on level of compliance in taking Vitamin C tablets. The groups were: (1) self-monitoring (i.e., the subjects were required to record the time at which each medication was taken); (2) taste (subjects were provided with flavored tablets); (3) taste plus self-monitoring; and (4) no treatment control group (i.e., subjects continued baseline procedures). The first phase of the study showed insufficient control of compliance behavior with the self-monitoring groups (i.e., self-monitoring and taste plus self-monitoring having only slightly higher levels of compliance than the remaining two groups). Due to the poor results, response-cost procedures were introduced (i.e., $1.00 of a total deposit of $9.00 would be forfeited

each week in which subjects did not receive a compliance score of two or better). The results showed a sharp increase in compliance for all subjects with the self-monitoring plus response-cost groups having the highest levels. It is not entirely clear, however, whether the results demonstrated were due to the reponse-cost program or to the fact that the subjects were now aware that their compliance behavior was being monitored.

In two of the most recent articles on compliance both sets of authors incorporated token systems in their treatment procedures to try to increase compliance with their subjects. Lowe and Lutzker (1979) examined the effects of written instructions and a point system upon compliance of three behaviors: (1) foot care; (2) dieting, and (3) urine testing. The subject was a 9 year old diabetic girl who had a history of severe noncompliance for these three behaviors. The results showed the memo condition (instructions) was relatively ineffective in increasing foot care and urine testing, but did eventually appear to facilitate proper dietary behaviors. When the point system was introduced the compliance for foot care and urine tests increased to 100% and was maintained.

Dapcich-Miura and Hovell (1979) looked at the effects of a token reinforcement procedure on a 82 year old coronary patient's complex medical regimen. The token procedure was introduced in a multiple baseline and reversal single-case experimental design. The results showed that the reinforcement contingency was responsible for improving three specific behaviors: (1) walking twice a day, (2) consumming a minimum of three glasses of orange juice a day, and (3) consumming all pills.

In summary, there were still some studies in the 1970's which tried to identify behavioral characteristics and types of variables which might explain differences in patients' levels of compliance (e.g., Gillum &

Barsky, 1974; Soutter & Kennedy, 1974; Van Patten, 1974; Zifferblat, 1975) but generally the trend was towards behavior modification studies concerned with increasing levels of compliance in specific patients (e.g., Dapcich-Miura & Hovell, 1979; Epstein & Masek, 1978; Haynes, 1975; Lowe & Lutzker, 1979, Magrab & Papadopoulou, 1977). There also was a review article written in the 1970's by Haynes. He reviewed 185 studies and concluded that only a small number of variables have demonstrated consistent relationships with patient adherence. These were: (1) "psychiatric" diagnosis, (2) complexity, duration, and amount of change in regimen, (3) inconveniences of operation of clinics, (4) inadequate supervision by professionals, (5) patient dissatisfaction, (6) inappropriate health beliefs, (7) noncompliance with other regimens, and (8) family instability. He also found that those that did not yield consistent relationships were still: (1) demographic factors, (2) personality characteristics, (3) patient knowledge, (4) health status, (5) social norms, and (6) patient-provider interactions (Haynes, 1976).

Recommendations for Compliance Research

The pre-1970 research on patient compliance is best described as being concerned with personality trait research to determine what factors may influence patient compliance. Such research was of limited utility. It wasn't really until post-1970 that researchers directly investigated ways to increase compliance behaviors of patients. Unfortunately, this area is still very poorly researched but the few studies conducted have provided strong reasons for optimism.

Pomerleau (1979) offers one of the most recent viewpoints on future directions for improving compliance, including:"(a) educating the patient concerning the regimen and its rationale, (b) making use of self-control

techniques, (c) tailoring the regimen so that its requirements fit the patient's daily routine, (d) shaping the desired performance (in complex treatment schedules), and (e) making full use of social support for adherence from family, co-workers, employers, and so forth" (p.659). Except for Pomerleau's first point, where there have been several studies which have shown that increasing the patient's knowledge of medications and disease has little or no effect upon levels of compliance (e.g., Miller et al., 1974; Sackett et al., 1975) I strongly agree with his ideas.

Besides suggestions for improving compliance, measurement problems must also receive careful examination. For example there is still controversy over the sole use of patient self-reports or pill counts as the measurement tools for medical compliance. Many studies have illustrated the inaccuracy of these methods (e.g., Roth et al., 1970), while others have found self-reports (for example) when paired with other assessment procedures to be reliable (e.g., Korsch & Morris, 1969). The use of serum or urine tracers appears to be a more objective system, but there are problems with varying definitions of compliance behavior as well as government drug agency restrictions. Pomerleau and Brady (1979) suggest that we try to devise ways of validating changes in compliance behavior without exclusive reliance on self-report or clinical outcome. Given all these concerns about measurement it seems reasonable for future research to use a combination of compliance measures rather than relying on only one technique.

Identifying specific populations to investigate in future compliance studies should be another concern. While some studies have accessed actual populations with specific disorders such as diabetes (e.g., Lowe & Lutzker, 1979) there are still other studies which have accessed

traditional research populations such as college students because of their ease of accessibility (e.g., Epstein & Masek, 1978). The use of a college population in this later study becomes even more of a concern because it was the the only study to try at least one portion of the recommended self-control techniques. To determine the efficacy of a complete self-control program it must be tried with a more relevant population.

Finally, while the problems and disorders studied in the patient compliance area have accessed some different disorders such as hypertension and diabetes, there are still others such as arthritis and glaucoma which have yet to be investigated. This becomes especially important given the higher incidence of chronic disorders in our society today as compared to 20 years ago (Epstein & LaPorte, 1978).

Appendix B

Review of Self-Control Literature

Self-control will be defined as the process by which an individual alters the probability of one of her/his responses by altering the variables of which that response is a function (Skinner, 1953). Skinner adds that self-control entails performing a behavior which manipulates the environment in such a way as to affect the probability of a target behavior or the controlled response. For example, he writes: "We may close or draw curtains to eliminate distracting stimuli or achieve the same effect by closing one's eyes or putting our fingers in our ears. We may put a box of candy out of sight to avoid overeating" (Skinner, 1953, p. 223).

Since Skinner's original formulation, several other definitions have been proposed. Thoresen and Mahoney presented a definition that conveys the general view reflected in the literature. They suggested that self-control is evident "when in the relative absence of immediate external constraints, a person engages in behavior whose previous probability has been less than that of alternatively available behaviors" (Thoresen & Mahoney, 1974, p. 12). In addition to Thoresen and Mahoney there have been a few other authors who have added significantly to the initial formulation (e.g., Bandura, 1971; Ferster, Nurnberger, & Levitt, 1962; Goldiamond, 1965; Homme, 1965; Kanfer & Phillips, 1970; Watson & Tharp, 1972). The basic premise offered by the majority of these authors is that most human behavior is maintained and altered in the absence of immediate external support and feedback (Jones et al., 1977). In support of this premise research has demonstrated that individuals are capable of

exerting some control over their own behavior by utilizing self-generated stimulation or by modifying or altering variables in the environment to maximize the probability of a particular response (Jones et al., 1977).

Problems of self-control usually fall into one of two categories, behavioral excesses or behavioral deficits (Kanfer & Phillips, 1970). In the first category, subjects engage in a behavior pattern that is self-defeating or injurious (e.g., obesity, excessive smoking and drinking). In the second category subjects suffer because they engage in certain behaviors only very infrequently (e.g., inability to study, sexual inactivity, patient non-compliance). For problems in the behavioral excess category it is the task of the therapist to help clients reduce the probabilities of the occurrence of such behaviors. For problems in the behavioral deficit category it is the task of the therapist to help clients increase the probabilities of these responses.

Self-control treatment procedures have been usefully conceptualized in a three-stage model (e.g., Kanfer, 1971; Karoly & Kanfer, 1974). The three phases are: (1) self-recording (also known as self-monitoring), (2) self-instructions (also known as prompts or instructions when they involve overt stimulation), and (3) self-reinforcement. I will now briefly review each of these three phases.

Self-Recording

In this procedure individuals assess the quantity and/or quality of their behavior. The initial use of self-recording in clinical research was as a method for gathering data prior to intervention (Kazdin, 1974). However, reports of it's reactive effects prompted the use of this procedure as a therapeutic intervention. For example, having a child self-

record his attending behavior in class resulted in an increase in this behavior (Broden et al., 1971). Similarily, having a child self-record class attendance resulted in an increase in this behavior (McKenzie & Rushall, 1974). Conversely, having a child self-record inappropriate responses such as talking out in class and aggression have resulted in decreases in these behaviors (Broden et al., 1971; Lovitt, 1973). Cautela (1971), along with other researchers, has made the assumption that the reason self-recording changes behavior is through its elicitation of covert self-reinforcing or self-punishing responses.

However, as an isolated procedure self-recording has not been universally effective (O'Leary & Dubey, 1979). For example Mahoney (1974), Nelson (1977), and Turkewitz, O'Leary, and Ironsmith (1975) all found self-recording to be ineffective. On the other hand, Broden et al., (1971), Herbert and Baer (1972), Nelson, Lipinski, and Boykin (1978), and Sagotsky, Patterson, and Lepper (1978) all found the procedures to be effective. Because of these inconsistent results, researchers have suggested that a number of procedural variables need to be considered. These include instructions to the self-recorders, criterion setting for the self-recorded responses, discriminative stimulus characteristics of the self-recording apparatus, and external monitoring of the self-recorded behaviors (Burg, Reid, & Lattimore, 1979).

Thoresen and Mahoney (1974) identified self-recording as the crucial first step in the acquisition of self-control skills. Logically then, the first step in developing self-regulatory skills in clients should be to develop accurate self-recording skills. Self-recording, like external monitoring, can involve any number of responses to be recorded as well

as various ways to record them. Both the target response and the self-recording response can vary from the simple (e.g., recording a check for each problem finished), to the complex (e.g., describing behavior, its consequences and antecedents).

Comparitive research indicates that self-recording is just as effective as external monitoring when both are followed by reinforcement. For example, Bolstad and Johnson (1972) compared self and external recording procedures with a group of disruptive first and second grade children. Both groups were rewarded on the basis of these assessments. These children showed significantly more improvement than no-treatment control children, and no differences were observed between the self- and external assessment. Fredericksen and Fredericksen (1975) obtained a similar result with mildly retarded children as did Wood and Flynn (1978) with predelinquent youths.

Summary. Self-recording has been found in some studies to have a reactive effect and to result in improvement of self-recorded behaviors. However, there have been other studies which have found self-recording not to be effective. When used in conjunction with rewards self-recording has been found to be as effective as external recording.

Self-Instruction

Self-instruction is defined as verbal statements to oneself which prompt, direct, or maintain behavior. The initial documentation of the effectiveness of self-instructions was provided by Luria in 1961. On the basis of his work and that of other Soviet investigators with children, Luria proposed three stages by which the initiation and inhibition of voluntary motor behaviors come under verbal control. During the

first stage, the speech of others, usually adults, controls and directs a child's behavior. In the second stage the child's own overt speech becomes an effective regulator of his behavior. Finally, the child's covert, or inner, speech assumes a self-governing role (Meichenbaum, 1974). It appears that self-instruction research grew out of earlier research on instructions. Data on the use of instructions showed them to to be effective controlling devices in changing behavior (Craighead, Kazdin, & Mahoney, 1976). However, self-instruction training was not really systematically investigated as a behavior modification strategy until the late 1960's and early 1970's (Craighead et al., 1976).

Several researchers found self-instructions to be effective in improving children's performance on a variety of tasks (e.g., Bem, 1967; Hartig & Kanfer, 1973; Meichenbaum & Goodman, 1969; Monahan & O'Leary, 1971; Palkes, Stewart, & Freedman, 1972). From this research with children at least four factors were found which appeared to influence the effectiveness of self-instructions: (1) children need to actually implement the instructional procedure, (2) the children need to use the self-instructions to influence behaviors at which they are skilled, (3) the children need to have been reinforced for adhering to their self-instructions in the past, and (4) the focus of the instructions needs to be on behavior most subject to positive consequences (O'Leary & Dubey, 1979).

The use of self-instructions as a therapeutic technique was first systematically studied by Meichenbaum and Goodman (1971). In this study a group of impulsive and hyperactive children were trained to instruct themselves on how to perform various tasks. Since then self-instructions

have been used with a variety of behavioral disorders such as test anxiety (Meichenbaum, 1972) and schizophrenia (Meichenbaum & Cameron, 1973).

In a comparison of experimenter and self-verbalized instructions Meichenbaum and Goodman (1969) found no significant differences between these two conditions with kindergarten children. Yet they found that with older school children more control was established with external instructions, although self-instructions were also effective.

Summary. Self-instructions can be effective when used as the sole intervention procedure. Their effectiveness depends however on, frequency of use, the individual's skill at performing the task involved, introducing reinforcement contingencies for following her/his instructions, and relative consequences for the target behavior which is the focus of the instructions. Self-instructions can also be as effective as externally imposed instructions when used in conjunction with a reward system.

Self-Reinforcement

Self-reinforcement occupies a prominent position in various theoretical analyses of self-control (Jones et al., 1977). Although authors differ in their conceptualizations of self-reinforcement, most have argued that behavior can be acquired and maintained through the self-delivery of reinforcers contingent on performing specific responses.

Bandura (1971, 1976) proposed three defining properties of self-reinforcement. First the organism exercises full control over the reinforcers so that they are freely available. Second, although the reinforcers are freely available, they are self-administered contingent upon the performance of specific behaviors. Thus self-reinforcement implicitly involves the self-denial of reinforcing stimuli until the response requirements are met. Third, self-reinforcement also requires the adoption of performance

standards that determine the criteria for reinforcement. Bandura notes that such standards can be acquired either through direct training or through modeling influences.

A common problem encountered in the theoretical analyses of self-reinforcement is the relationship between the effects of self-reinforcement and the effects of external controlling influences. Thoresen and Mahoney (1974) conceive of self-control as being on a continuum. Therefore, Thoresen and Mahoney use Skinner's (1953) distinction between controlled and controlling responses. Controlling responses (such as the self-delivery of consequences) can be self-generated and can influence the probability of the controlled response. The controlling responses, however, are subject to external control. Thus, self-reinforcement is seen as a means to mediate delayed external control and specific target responses. A person and his environment are viewed as being in a complex reciprocal interaction. It is assumed that a person can modify the environment or the consequences of behavior to facilitate behavior change, but that self-controlling responses are partially dependent upon environmental variables (Jones et al., 1977).

Self-reinforcement has been used in a variety of applied procedures, in both clinical and educational settings. Applications have focused upon such problems as disruptive and academic behaviors in educational settings, weight control, depression, smoking, nailbiting, and dating amongst others (Jones et al., 1977).

Some investigators in the school setting have found external reinforcement to be more effective than self-reinforcement in developing and sustaining behavior change (e.g., Felixbrod & O'Leary, 1973, 1974;

Fredericksen & Fredericksen, 1975), others have found the opposite (e.g., Lovitt & Curtis, 1969), and some have found no difference (e.g., Glynn, 1970).

Probably one of the more popular areas in the use of self-reinforcement techniques is obesity. Unfortunately, from the point of view of isolating the effects of self-reinforcement, treatment usually consists of a multi-component behavioral package. However, this was not the case in a study by Mahoney, Moura, and Wade (1973). They contrasted the effects of self-reinforcement, self-punishment, self-monitoring, and an information-only control procedure. Results showed that subjects in the self-reinforcement condition lost significantly more weight than subjects in the other groups. In a later study, Mahoney (1974) contrasted the effects of two self-reinforcement procedures with the effects of self-monitoring alone. Results showed that the two self-reinforcement procedures produced more enduring weight losses than did self-monitoring alone.

In a comparison of external versus self-reinforcement procedures Jeffrey (1974) compared the effects of two self-reinforcement procedures with external reinforcement for weight losses. At weekly meetings with the therapist, external control subjects received money from their initial deposits for meeting goals. Self-reinforcement subjects were given the opportunity to privately take bank cheques from the experimental room contingent upon specified changes in their behavior. In one self-reinforcement group subjects were told they would receive the balance of their deposits at the end of the program regardless of weight changes. Subjects in the other two groups were told they would forfeit any part of their remaining deposit at the end of the program. All

three procedures were equally effective in producing weight loss during treatment, yet only the self-reinforcement procedures led to greater weight losses in follow-up.

Summary. Self-reinforcement is clearly the most powerful of the three self-control procedures. However, like the other two procedures, self-reinforcement has also produced some conflicting results. Some studies have found self-reinforcement to be more effective than external reinforcement, others have found it to be less effective, and still others have found no difference.

Some Final Comments

Earlier, some comments were made about the controversy over terminology in the "self-control" area. It was not the intent of this paper to do a theoretical analyses of this area and so therefore the term self-reinforcement was not used and instead the term self-delivery of rewards was used. However, in spite of all the methodological and theoretical concerns, these so called "self-control" techniques do work and have shown much applied promise. Thus while conceptual refinements are worthy achievements, they should not be perceived as detracting from the clinical significance of "self-control" procedures.

Appendix C

Criteria for Subject Selection

Criteria for Inclusion

Males and females age 21 to 75 years

Those fulfilling the criteria for diagnosis of active rheumatoid arthritis.

Criteria for Exclusion

Patients whose arthritis is satisfactorily controlled by current therapy.

Pregnant women, nursing mothers, or women of child-bearing age who are not following adequate contraceptive precautions and/or whose intention it is to become pregnant during the study perion.

Patients requiring (a) other non-steroidal anti-inflammatory (NSAI) analgesics which can not be discontinued, (b) concomitant gold or cotico-steroids (maximum prednisone 10 mg/day or equivalent) which has not been administered in a fixed, stable maintenance regimen during the preceding three months, (c) penicillamine, (d) cytotoxic agents, (e) drugs known to interact with the study medications.

Patients in whom joint surgery is contemplated during Part 1 of the study.

Anemia or any other hematological disorders such as leukopenia or thrombocytopenia, serious enough, in the opinion of the investigator, to preclude entry into this study.

Active liver disease.

Active gastrointestinal tract disease, including the presence of peptic ulceration and gastrointestinal bleeding or a past history of these conditions which, in the opinion of the investigator, precludes the

patient's entry into the study.

A known or suspected allergy to any of the study medications and/or other NSAI drugs.

History of unreliable drug intake and inability to cooperate in the testing procedure.

Significant renal disease (serum creatinine $\geq$ 2mg/dl).

Other diseases closely related to rheumatoid arthritis or other arthropathies.

Appendix D

Raw Data

Table 1

Physiotherapist and Patient Assessments of

Various Physiological Measures During Baseline and Treatment

	Week	Joints Tender	Joints Swollen	Grip Left	Grip Right	Pain	Activity	Pain Level
S_1	start	0	0	88	136	worse	mild	mild
	1	4	2	109	192	better	better	very mild
	2	16	2	83	138	worse	mild	mild
	3	6	4	116	201	mild	better	mild
	4	7	1	101	164	same	same	mild
Treatment	8	4	3	67	199	same	same	mild
	11	9	2	50	123	worse	worse	severe
S_2	start	7	10	65	92	-	-	moderate
	7	7	4	91	117	same	same	mild
	8	3	5	85	123	same	same	mild
	9	5	5	92	148	better	better	mild
S_3	start	8	8	115	98	worse	same	very mild
	7	4	2	93	94	better	same	mild
	8	3	10	105	93	worse	same	mild
Treatment	9	5	10	90	85	worse	same	severe
	13	4	11	93	79	better	same	very mild
	17	8	19	97	88	worse	worse	severe
S_4	start	6	17	62	56	same	same	moderate
	7	5	11	92	89	better	better	none
	8	2	8	64	72	same	same	moderate
	9	16	11	81	77	worse	same	mild/moderate
Treatment	13	16	15	69	66	same	same	moderate
	17	17	16	89	81	better	same	moderate

Table 2

Percentage Levels of Agreement Between

Individual Subject's Self-Monitoring Data and Pill Count Data

WEEKS

	10	11	12	13	14	15	16	17	18	19	20	21	$\bar{x}$
S_1	100	100	100	100	96	85	100	100	100	100	100	X	98.3
S_2	X	96	96	96	X	X	X	X	X	X	X	X	96.0
S_3	X	X	X	100	100	100	100	100	96	92	92	96	97.3
S_4	X	X	X	X	96	100	100	100	92	96	100	100	98.0

Total $\bar{x}$ 97%

Appendix E

Social Validation Questionnaire

Name: _____

Date: _____

1. Did you find the self-control package (i.e., alarm watch, cue cards, data sheets, reinforcement) useful?

   Yes ____ No ____ Partly ____

   Comments: _____

2. If you answered Yes or Partly to #1, which component did you find the most helpful? _____ Comments: _____

   If you answered No to #1 go to #6.

3. What was the second most helpful component? _____ Comments: ____

4. What was the third most helpful component? Comments _____

5. What was the least helpful component? Comments: _____

6. Did your family or friends get involved with your self-control package?

   Yes ____ No ____

7. If you answered Yes to #6, what kinds of things did they do? _____

   If you answered No to #6 go to #8.

8. Are there other ideas that you think could have been added to the self-control package which could have made it more effective for you?

_____

_____

_____

9. Do you have some special things which you do to help you rember to take your pills?

Yes _____ No _____

10. If you answered Yes to #9, can you describe these special things?

_____

_____

_____

11. Do you have any other problems or comments about this self-control package that you would like to mention?

_____

_____

_____

12. Did you notice any improvement in your arthritic condition?

Yes _____ No _____ Partly _____

If you answered Yes or Partly, can you estimate about when you noticed this improvement?

_____

_____

1. Considering the results you have just seen, comparing the before and after differences in your compliance rates, does this alter your perception about the effectiveness of the self-control package upon your compliance behavior?

2. Did you know your pill counts were being monitored?

   Yes _____ No _____ Comments? _____

3. Did you absolutely know which of the two pills were active and which one was the placebo?

   Yes _____ No _____ Comments? _____

Subject 1

1. Yes
2. Alarm watch
3. Cue cards
4. Data sheets
5. Reinforcement
6. Yes
7. "Dad, did you take your pills?" "Dad, your watch is buzzing."
8. No
9. No
10. N/A
11. Watch was good, got me into a routine
12. No

1. No, I thought it was good to begin with.
2. I figured they were.
3. No

Subject 3

1. Yes
2. Watch and cue cards
3. Watch and cue cards
4. Reinforcement
5. Data sheets (not helpful)
6. Yes
7. They said: "Did you reinforce?" "Did you take your pills?"
   Watch started it.
8. More than enough
9. Yes
10. Take with meals. Put tray of pills on table.
11. Bit of problem with with watch; too time consuming for data sheets
12. No

1. More positive about effect
2. Had an idea
3. No

Subject 4

1. Partly
2. Data sheets (presence helped to remember)
3. Cue cards
4. Reinforcement
5. Alarm watch
6. No
7. N/A
8. Still found data sheets helpful (even by itself)
9. Yes
10. After meals, take medication
11. Alarm watch wasn't useful (problem with adjusting the watch - too difficult and small to work)
12. No

1. Looks like I was more alert following the package.
2. No
3. No

   (kind of fun; something to think about)