**SUPPLEMENTAL DIGITAL CONTENT**

**A Stepwise Psychotherapy Intervention for Reducing Risk in Coronary Artery Disease (SPIRR-CAD) – Results of an observer-blinded, multicenter, centered trial in depressed patients with CAD**

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**A: Supplemental Methods**

**A1: Manual for SPIRR-CAD psychotherapy intervention**

(by Jordan J, Albus C, Fritzsche K, Beutel M, and Herrmann-Lingen C)

**A1.1 Introduction**

This manual specifies the psychotherapeutic procedure within the framework of the SPIRR-CAD trial which had been developed for patients with depressive symptoms that receive treatment for known coronary heart disease (CHD) in one of the participating centers. The aim of the treatment is to meet the requirements of the various affective patterns of disorder (i.e. depressive adjustment disorders, mild to moderate depressive episodes, dysthymia) by means of a gradual offer consisting of individual as well as group psychotherapy sessions.

The psychometric screening examination (HADS, DS-14) shows increased scores on the HADS depression subscale in all patients included. According to existing epidemiologic data we assume that at least 50% of those patients will simultaneously show increased scores on the DS-14 „Negative Affectivity“ and “Social Inhibition” scales. At first, three individual psycho­therapeutic sessions are offered within four weeks, after which the depressive symptomatology will be re-evaluated. An additional 20 group therapy sessions (once a week for a 6 months duration) will be provided if symptoms have not improved by then, followed by 5 sessions once a month for a total duration of one year.

The psychotherapeutic procedure is psychodynamically oriented, but also integrates established aspects of cognitive-behavioral and interactional treatment approaches. It meets the present standard of knowledge and is geared to the specific problems of CHD-patients with depression, negative affectivity in general, and social inhibition.

**A1.2 Individual psychotherapy**

The main focus of the three psychotherapeutic individual sessions is on building an empathic and trusting therapeutic alliance and on exploring the patient’s subjective experience. Hereby feelings of depression, helplessness and despair given the disease will be investigated as well as disappointment and mortification in the patient’s private life and previous treatment experience. If dysfunctional relationship patterns and maladaptive coping with the disease are unveiled they will be described and first options to overcome the same will be identified. Positive experience from psychotherapeutic sessions in form of understanding and possible improvement of the psychological condition will be used for possible subsequent group therapy treatment.

***Experiences underlying the psychotherapeutic intervention:***

* General assumptions of short-term psychotherapy (1,2)
* A helpful trusting relationship (2)
* Specific psychodynamic, interpersonal psychotherapy (3)
* Supportive psychotherapy (4)
* Specific elements of the psychotherapeutic treatment of patients with CHD (5-11)

***Aims of the psychotherapeutic intervention:***

* Improvement of depression and general emotional well-being
* Promotion of cooperation between patient and care providers
* Inclusion of the patient’s partner or significant others intending relief of depressive symptoms
* In case of insufficient symptom reduction motivation for further group therapy.

***Effective factors:***

The following factors proven effective in psychotherapy research for depression are employed:

* Quality of the therapeutic relationship as most important factor
* Problem actualisation of depressive patterns in the “here and now”
* Active help in problem solving instead of social withdrawal, e.g. in a session with the partner or in case of problems concerning doctors and nursing staff
* Activation of resources by promoting new positive experiences in the self-management.

***Therapeutic principles:***

The following principles are to be considered independently of the individual session’s content:

* Acceptance of the subjective nature or the patient’s experience
* Avoidance of rash interpretations of psychosocial conflicts
* Preservation of empathy and patience, even when negative attitudes and emotions are expressed that are hard to bear
* Avoidance of humiliation in relation to problematic principles and behavior damaging one’s own health (e.g. smoking, overeating, sedentary lifestyle)
* Cooperation with cardiology staff
* Objectives that are flexibly oriented around the patient’s capacities.

**Setting**

The initial contact usually takes place on the wards of the cardiology department. If needed, e.g. to create an uninterrupted atmosphere or if patients are discharged before the initial contact, the patient attends the psychosomatic out-patient clinic. With regard to the relatively short stay on cardiologic wards subsequent sessions then take place in the out-patient department.

The duration of sessions is 50 minutes each. For clients from a catchment area of approximately 30 km attending the out-patient clinic for two to three sessions was regarded as reasonable.

**Contents of sessions**

***Initial contact:***

* Creating a therapeutic alliance
* Taking a bio-psycho-social case-history
* Assessment of subjective illness perception and coping strategies.

***Second session:***

* Improvement of perception and differentiation of how depressive symptoms are expressed, especially in social relationships
* First stimulation to improve negative emotions, dysfunctional relationships and maladaptive illness behavior.

***Third session:***

* *If possible:* Inclusion of the partner or significant others
* Further treatment planning
* Activation of resources.

To create continuity the psychotherapist summarises the content at the end of each session and clarifies if the patient agrees with the therapist’s evaluation and where possible differences lie. Areas to be deepened and such ones suggested by the patient will be kept in mind for the subsequent session. In the beginning of each new session a review of the last conversation will be given and new thoughts, feelings, and experiences arisen in the meantime will be discussed.

**The initial contact**

The therapist endeavours to create an open atmosphere that encourages the patient to talk. In accordance with a narrative structure of conversation the patient talks freely, so somatic problems and psychological strain alike will be brought up without specific therapeutic intervention. Following an open question aiming at the current situation and present symptoms the patient will describe his/her negative emotions in detail, but also somatic complaints and treatment experiences, e.g. invasive diagnostic and therapeutic interventions. The psychotherapist explores all symptoms, their intensity and occurrence and, in case of somatic complaints, encourages the patient to demonstrate their localisation, e.g. retrosternal pain, and related restrictions, e.g. when bending down. By means of explaining symptoms and related restrictions the patient also enables the psychotherapist to gain an insight into his/her inner world: the patient’s symptom exploration does often not only provide a list of complaints but also pictures of insistent intensity.

The patient’s language, accompanying emotions, facial expressions and posture can indicate hidden unsolved conflicts and traumas (12).

By inquiring the bio-psycho-social background the psychotherapist gains insight into the patient’s past and present life. This includes family details and experience in dealing with somatic illness and mental strain. Psychological and physical resources, past and present protective factors and coping strategies when dealing with illness and burden will be salutogenetically investigated.

Emotional comments by the patient will be registered attentively and considered as possible indicators of unsolved emotional strains. Defense mechanisms such as denial, projection, and phantasies of omnipotence are accepted as useful attempts for the patient to control the situation. Insight into psychosomatic interrelations and motivation for psychotherapeutic treatment cannot be assumed a priori. Negative countertransference soon arises in such patients. It can be controlled for more effectively if the therapist imagines that this is not the patients’ fault, that patients are hurt by their illness and thus in need of a benevolent and active initiation of relationship by the therapist.

***Example[[1]](#footnote-1):***

*PT: How did you feel when you learned about your heart disease?*

*Pat: Well, how should I’ve felt, ok, I guess.*

*PT:* *I can imagine and I also know from other patients that it can be quite a shock to be diagnosed with such a disease.*

*Pat: Yes, that’s true.*

*PT: So what did you feel then? Please tell me some details.*

Specific interventions aim at the patient’s fear to be mentally ill and in need of a psychologist in addition to suffering from heart disease. The patient is encouraged to talk about his/her fears and sorrows with regard to the illness, which are confirmed as understandable reactions within the coping process but will not be analysed any further at this point.

Descriptions of past and present relationships with parents, friends, and partner show detailed pictures of the history of relationships and patterns of interaction. How did the contact between patient and significant others change because of his/her heart disease? How does the patient see himself/herself? How is he/she regarded by significant others? These reports indicate dysfunctional social contacts, habitual patterns of relationships and conclusions regarding personal bonds.

On the basis of this information the psychotherapist can create first hypotheses regarding the structure of the self, defence mechanisms, maladaptive patterns of behavior, patterns of bonding and strategies to cope with the illness.

Another aim of the initial contact is to investigate and to deal with subjective illness perceptions. Hereby the therapist accepts the patient’s position and withholds own thoughts concerning CHD. Possible questions to assess subjective understanding of the illness and its treatment could be as follows:

* Do you have a possible explanation how your heart disease evolved?
* Why do you think did the illness arise at this particular point in time?
* How serious do you see your illness?
* Which therapy seems the most effective to you?
* Do you feel to be able to control the progression of the disease?

Coping strategies can be explored by means of specific questions:

***Active problem-oriented coping:***

* Do you believe that you could actively improve your health? Would you like to have more information about the disease and did you already look for such information?

 ***Distraction and self-comforting:***

* When did you last do something pleasant?
* Do you know the feeling of comforting yourself with the idea that others are worse off than yourself?

***Questions regarding resignation and self-blaming:***

* Have you ever thought that life has lost its meaning?
* Did you ever feel that you deserve it?

Information on factors leading to a myocardial infarction (MI) and its treatment, on risk factors and strategies for modification, information on possible consequences of an MI regarding sexuality, social relationships, work and social life are not provided automatically but according to the need of the individual patient.

***Example:***

*PT: Can you imagine how stress can damage your heart?*

*Pat: Ah no, I actually don’t think that that’s so important, I’ve always been somewhat agitated.*

*PT: One cannot answer such a question across the board. Recent research, however, shows many findings on this topic. If you like, I could tell you something about it and we can jointly try to identify what might be relevant in your case.*

*Pat: Well, then let’s face the facts.*

The session must also include a clarification of possible goals of the subsequent psychotherapy sessions. These should preferably be framed precisely, e.g. agreement on a joint session with the patient’s wife/husband instead of a general wish for a better couple’s relationship.

After the initial contact the patient should feel well understood, emotionally relieved and thereby motivated for additional psychotherapeutic sessions.

**Second session**

The aim of the second session is to handle depressive symptoms and other negative affects more flexibly within interpersonal relationships as well as to understand their impact on maladaptive illness behavior. At the beginning of the session the therapist leaves sufficient space for the description of the somatic condition, experiences with physicians, nursing staff and diagnostic and therapeutic measures. Relief and consolidation of the therapeutic relationship are brought about by verbalising fears and disappointments.

The patient’s descriptions, both his/her current experiences and past records, are availed of to teach him/her the perception of emotions. Each expression, verbal or non-verbal (e.g. facial expression, body posture, baled fist), will be empathetically picked out as a central theme.

Apart from desired affects, subjectively undesired affects should also be accepted at this point. This causes psychological relief and leads to the development of a coherent feeling of self. Thereby abilities to reflect on oneself and to contest in conflict situations will be improved.

Mirroring emotions to the patients by offering the therapist’s perception as a proposal avoids restricting him/her to simple affirmation but invites him/her to specify and possibly correct the therapist’s impression. The patient then has the option to decide whether his/her feeling corresponds with the therapist’s or if a change of subject should be initiated. Non-verbal emotions will also be named in terms of a proposal: “I have the impression you are angry.” “You seem very depressed right now.”

The focus on life strains, relationship problems and daily hassles is one possible option at this point.

***Example:***

*A patient having suffered two myocardial infarctions within one year and having been off sick for the last three months.*

*PT: Do you have any idea what factors could have furthered the emergence of two heart attacks within such a short period of time?*

*Pat: No idea, possibly stress?*

*PT: Yes, that’s possible. Could you please tell me what you mean by stress?*

*Pat: Well, I had a lot of trouble at work.*

*PT: What caused the trouble?*

*Pat: I have a colleague who keeps bullying me.*

*PT: How did you deal with that?*

*Pat: Why me? This isn’t my fault!*

*PT: Well, I can understand your anger but I was just wondering if we could find a way to deal with that colleague of yours. This would reduce your stress and you might gain stability health wise. What exactly did you feel when he or she attacked you?*

If an important life event is presented astonishingly calm then the therapist could reply to this unclear or assumed emotion: ”You seem very calm to me when talking about this incident.” If the patient’s report changes suddenly, showing a discontinuity as regards to content, the previous content will be summarised and the missing link pointed out: “I don’t understand this unexpected step in your report.” Repetitions on part of the patient occur when the psychotherapist misses a hidden emotional message. Therefore, it is crucial to recognise such repetitions and their underlying emotional contents in order to take up the hidden feeling.

By using the stress model, specific interventions explain psychophysiological links between negative emotions and the following physiologic reactions.

The vicious circle model is another possibility to demonstrate connections between strain, somatic reactions, fear, increase of tension and symptoms.

***Dysfunctional habitual patterns of relationships and maladaptive illness behavior:***

Understanding habitual, dysfunctional forming of relationships aims at strengthening the patient’s self-esteem and the quality of interpersonal bonds. The patient learns about the dysfunctional and irrational nature of images or models of himself/herself and others. Withdrawal from relationships can cause misjudgements of one’s self-evaluation and strengthen existing (negative) concepts of oneself and the world. Relationship patterns will be evaluated in terms of typical examples given by the patient. Satisfying alternatives will be explored. Depending on the patient’s motivation, role plays can come into action.

Chronic maladaptive illness behavior like difficulties to adhere to physicians’ advice or frequent use of medical services can significantly worsen the prognosis of CHD. Frequently patients are aware of the damaging nature of their behavior but feel unable to change it. They fear blame, shame, and paternalism. Therefore, there is a need for a considerate approach to the topic whereby the patient should always be able to save face. Moreover, it should not be picked out before the second session until a reasonably trusting contact has been established. If the patient discloses his/her maladaptive “secret” it is important to accept it as a solution for the time being and to regard it as the only way to secure autonomy that some patients could avail of so far.

***Example:***

*PT: You told me that you suffered severely from angina pectoris over the last months. How did you deal with the attacks?*

*Pat: Well, when I couldn’t take it anymore my wife called the ambulance that took me to the intensive care unit.*

*PT: Did you try to help yourself before that?*

*Pat: Ah, at first it wasn’t that bad but then it got worse so I had to take the spray.*

*PT: Did you take it that late?*

*Pat: I thought it would go away by itself.*

*PT: So why did you hesitate?*

*Pat: When it started I didn’t want to go to hospital!*

*PT: Were you so shocked that you somehow forgot to take it?*

*Pat: Yes, I guess so.*

*PT: Thereby, I could imagine that you would be interested in preventing a hospital admission after all. Together we could try to find out why you couldn’t manage so far.*

**Third session**

The aim of the third session is to involve the patient’s partner or significant others and to complete this treatment phase. Through social contact it helps to strengthen partnership resources and to reduce depressive feelings, fears and apprehensions. The following topics can be emphasised in couple or family sessions:

* How does the couple or family talk about the CHD?
* Which role changes evolved as a result of the illness?
* In what other way did the relationship between partners or within the family change as a result of the illness?
* How did CHD affect the couple’s sexuality?
* Which resources are available for the couple/family to cope with the situation?
* Is it possible to improve social support within the family?

If it is not possible to arrange a couple or family session, one session can be used to take the above questions as central theme in the individual.

The last session also covers fears and hopes with regard to future treatment, necessary interventions (catheter dilatation, bypass surgery) and professional future. The completion of this treatment phase will be talked about and group therapy will be prepared if indicated. Together with the patient short term and long term goals will be developed as well as their feasibility evaluated. Psychological and social resources will be named and included into the course of the treatment as possible support.

**Conclusion**

This individual psychotherapeutic intervention is problem-oriented in the „here and now“. Its main goal is to enhance strategies for coping with illness as well as to partly improve ways to deal with depressive symptoms, negative emotions and interpersonal problems. Apart from the therapeutic alliance, general ways of action in psychotherapy (13) like coping support, resource orientation, and problem update are accounted for.

After the individual psychotherapy, patients with ***persistent depressive symptoms*** should feel encouraged and ready to further join the following group therapy.

A1.3 Group psychotherapy

**Theoretical background**

Since the beginning of systematic research in psycho-cardiology around 1936, there is increasing evidence that symptoms of depression play a major role in the aetiology of CHD, and even more in coping with illness and in prognosis. Nowadays, many authors believe that frequent patterns of ambitious, high-achieving, passivity-avoiding attitudes in patients with CHD are due to an underlying unconscious depressive conflict, i.e. perceived lack of recognition, uncertain role identification etc. (14). Extreme activity, eg the Type A pattern, is believed to be a defence mechanism against overt depression. This defence can be weakened by myocardial infarction so that depression can arise. Some patients may react by augmenting defence and thus will not be detected by our screening procedures, others may feel depressed but struggle with the emotional consequences which may lead to social withdrawal and latent anger. Psychodynamic group therapy has then to deal with the different expressions of depression like discouraged feelings and social withdrawal (which both constitute major parts of the Type D pattern, i.e. negative affectivity and social inhibition) or non-adherent and quarrelsome behavior. These elements will become manifest in the dynamics of the group; they need to be taken up and handled with great care, a lot of experience and supervision.

**Treatment goals**

It is crucial that CHD patients must actively be motivated for a psychodynamic group approach, in order to make certain personality patterns, suggested to underlie persistent depression (e.g., the Type D pattern), accessible for such an intervention (10,11). Therefore, psychodynamic treatment technique was broadened by supportive expressive interventions (see 2) and cognitive-behavioral modules (The Hook; 15), LifeSkills (16,17) that have already been evaluated successfully in other studies (RCPP; 18).

Within the intervention, specific experiences are to be dealt with and modified that have been shown to unfavorably affect the course of the illness. Besides depression, these include various styles of interaction and maladaptive relationship patterns that have developed on the basis of the individual patient’s biographic experience and lead to distinct negative affects within social relationships. All patients share an unspecific negative affectivity following social interactions whereby it is important to note that psychodynamic constellations, immediate interactions, as well as resulting negative emotions can differ from each other.

Frequently arising negative affects lead to chronic disappointment in interaction partners by suggesting that many patients are not aware of themselves. This in turn provokes patients’ devaluation of and hostility towards others as well as social withdrawal. Comparable constructs of proven relevance include anger, hostility, irritability, impatience and the Type-A behavior pattern in the broader sense.

Aim of the treatment is to analyse and deal with individual maladaptive cycles of interaction as well as to elaborate alternative ways of action based on altered cognitive structures and newly gained understanding of own emotional experiences.

According to the psychodynamic view it is necessary to reach deep layers of experience that also touch underlying conflicts or traumatic relationship experiences in order to achieve this particular treatment goal. On this basis a broadening and alteration of social relationship patterns is intended that enables patients to gain new and above all positive experience in interacting with others.

It is only possible to achieve these goals if a stable atmosphere within the group has been established and if psychological ways of dealing with the illness have been discussed (inauguration phase to establish a constructive group setting). In this specific subgroup of CHD patients it can be taken for granted that a risk-reduced lifestyle concerning all cardiovascular risk factors is necessary and that this topic is discussed within the group. Coping with the illness also plays an important part in this context. Both aspects (risk factors and coping with the illness) are secondary but indispensable contents and aims of the intervention.

**The focus of group therapy**

All interventions within the group therapy are solely aimed at four areas:

* Coping with the illness, including eg, feelings of being defeated, insecurity and loss of role gratification
* Dealing with emotions, including eg, coping with dejection and lack of energy
* Change of lifestyle (risk factors)
* Shaping of social relationships and unconscious conflicts and relationship patterns.

This means that the therapists need to evaluate all reports and interactions regarding their relevance to the above. Moreover, an attempt should always be made to focus both the material provided by the patients and the therapeutic intervention onto the above areas.

***Background:***

It can be assumed that CHD creates a significant, often serious or even traumatic psychological burden and that all persons affected need to consciously and unconsciously deal with this biographical crisis. Subsequent fears of death and dying as well as related psychological coping (or unconscious defence) will play a central part in patients’ lives. Dealing with uncertainty and fear determines how cardiac symptoms are dealt with and alters the emergence and the processing of emotional disturbances within the context of coping with the illness. This also influences attempts to change one’s lifestyle (reduction of risk factors).

According to recent cardiology guidelines (19), smoking cessation, reduction of high fat diet, and expansion of physical exercise are crucial factors in secondary prevention. This dimension needs to be part of the group therapy both in order to facilitate required behavior change and to increase credibility of the intervention for patients mainly considering their illness as a somatic disease.

Group therapists regard the characteristics of the patients’ social relationship styles as central aspects of the intervention: Both coping with the disease as well as modulating risk factors will be looked at and worked on with regard to the patients’ social bonds, especially their partnerships. We believe that a psychodynamically oriented treatment technique is most suitable as not only the nature and experience of social relationships are covered but also because change can be initiated based on the analysis of unconscious processes assumed to have a crucial impact on risk behavior as well as on subsequent coping strategies. Within the group, dysfunctional interactions and experiences will be reproduced and can thus be worked on (repetition, resistance, transference).

To foster and purposely modulate this process two additional cognitive-behavioral techniques that have been clinically proven and published are added to the psychodynamic approach. Both aim at helping patients to cope with negative affects and shape their social relationships in a satisfactory way. First, after the initial five introductory sessions (aiming at building trust and group coherence) elements of the so-called “LifeSkills” programme by Williams & Williams (16,17) will be implemented as technical tools; furthermore, elements of the so-called “Hook” technique described by Powell (15) will be included.

The inclusion of structuring elements into the group process corresponds with the needs of many patients for active coping strategies. Furthermore, these elements will foster the working alliance and group cohesion. In the same time, adaptive defence of depression is augmented, what conversely will help patients to better integrate depressive feelings by learning that both sides, i.e. depressive feelings and active coping, belong together and can be tolerated.

***The Hook****:* This specific and targeted intervention had been developed and tested within the framework of the Recurrent Coronary Prevention Project (RCPP) and refers to defined interventions that can be scheduled precisely, focusing on negative affects. “The Hook” is a cognitive restructuring strategy that aims to “replace an attitude associated with reactivity to a stressor with an alternative attitude that is associated with stress resistance“ (15, p. 318). Affects involving anger and irritability are mainly targeted. At first, patients are encouraged to talk about events that occurred during the last few days and caused anger, irritability, or strong feelings of impatience and tension. The other group members are allowed to ask short questions but not to make any comments until everyone had a turn. The first step in dealing with the events is to ask oneself, at which point the situation could have been controlled better and what options to do so would have been available. On this basis, each patient’s reaction (inner level as well as actual behavior) will be evaluated and cognitive modifications will be looked for. The main idea is to identify whether the interlocutor’s behavior can be altered (which is often unlikely) or if one’s own attitudes can be modified (costly but possible).

The second step of the “Hook” intervention is to jointly identify three elements that elicit negative emotions: All too ***fast*** reactions to a basically ***minor*** (possibly insignificant) and mainly ***unexpected***stressor. Those three elements (fast reaction, minor reason, unexpected constellation) will be specifically worked through for all members of the group.

The third step of the intervention has given the technique its name. The fact that there is a maladaptive automatism that causes all participants to be rash in their reactions will be worked out. A cognitive mechanism will be opposed: Whenever a “hook” situation becomes noticeable (i.e. a situation eliciting anger, impatience, negative emotions), patients should step back and ask themselves if they should just “swallow” it like fish swallow a fisherman’s hook or if they find an alternative reaction. A blinking light bulb is imagined that reminds the person that this is a so-called “Hook situation”.

The aim is to learn: “this is a malignant trigger for me that I usually react to in a way that leaves me with negative feelings.” Only then is it possible to learn that there are alternative internal and external reactions that change one’s perception of the stressor, even when the stressor itself cannot be changed. In concrete terms this means that another person criticizes something or uses negative comments to express critique. In this case cognitive restructuring could occur as follows: “this person actually says something about himself or herself, not (mainly) about me. I will only enquire about it and ask to consider something but I won’t explain anything or defend myself.”

During the course of various group sessions participants will be asked to talk more and more about their experiences with “Hook” situations and to help each other to develop clever and relaxing strategies.

From the psychodynamic point of understanding, feeling oneself into others, and emotional decentration will be fostered. A reduction of narcissistic vulnerability is striven for that also aims at reducing the frequency of reacting to environmental cue in a way that repeats earlier life experience while becoming maladaptive in the current situation.

The ***LifeSkills technique*** pursues similar goals: Developed and tested by Williams & Williams (16,17) it refers to an unspecific program of health psychology education comprising a total of 12 structured sessions described in a manual. Sessions 3, 4, 6, and 7 match the intentions of the study:

3. Judging negative thoughts and feelings as well as possible ways of action

4. To overcome cumbering negative thoughts and feelings

6. To assert oneself appropriately

7. Learning to say NO.

The course of each session is described in detail in the manual, providing various examples. Recently, a German translation of the manual (20; German Version by Albus, unpublished) was included into another clinical trial, and preliminary results indicate good feasibility of the concept in German cardiac patients (21). From diary entries, intended to be a kind of homework and brought along to each session, situational aspects, development, and attempts to try new ways of action will be worked through with strong guidance by the therapists.

**Setting of group therapy**

The location needs to be sufficient in size and brightness. Disrupting outside noise should be avoided if possible (e. g. noise from a building site, ambulances, etc.). Therapy shall be held in groups of 4-10 participants. General rules (reliablilty of participation, confidentiality etc., see below) shall be explained explicitly in the first session.

**Phases of therapy**

To guide the therapists’ attention and to standardize the intervention, the 25 sessions will be grouped into three phases (see 22).

***First Phase: Development of group coherence: 1st to 5th session***

This phase is about getting to know each other, explaining aims of the treatment and principles of group communication, and having a conversation about experiencing the illness, illness-specific diagnostics and therapy.

***Specific guidelines:***

1st Session: All patients introduce themselves (and talk about their illness, their family and job situation). Aims of the intervention, patient selection criteria (also see next paragraph), and rules of communication will be explained and discussed.

2nd Session: All patients describe their experience with the illness, its treatment, and rehabilitation whereby reactions of friends and family should be of special interest for the therapists who can enquire accordingly.

3rd Session: Here a psychoeducative session will be held where so-called traditional and psychosocial risk factors and their interdependence will be explained and advice on
 protective factors will be given.

4th Session: Negative emotions frequently observed within the group process will be evaluated as well as how patients tend to react as a consequence.

5th Session: Continuing with the contents of the 4th session.

The initial phase is crucial for both atmosphere and the group’s ability to work together. Therefore criteria for patient selection, the general therapeutic attitude and the four central aims will be explained. Moreover, details on the duration of each session and the total duration of the intervention will be given. Patients should not be labelled as being depressed but the intervention should be explained as having rather been designed in a way that four aims relevant to all CHD patients are covered, for which selected participants with some degree of emotional distress seemed most suitable. The psychological adaptation to the illness and the adaptation of lifestyle to the new situation are named as main concepts.

During the first sessions it is frequently pointed out and exemplarily worked through that coping with problems, tension, and dissatisfaction is relevant and that changing the expression of hatred, hostility, anger, and disappointment plays a crucial role for most people.

So far it has been very effective to initially explain the following rules of communication for use within the group and to display and leave them somewhere in the room where everyone can clearly see them:

*Group rules*

1. The group session takes 90 minutes
2. Being late should be avoided as it interrupts the entire group
3. It is important that everyone attends each session
4. Everyone is responsible for himself/herself
5. Wishes should be expressed openly
6. Each participant is free to say NO at any time
7. There is no prattle during the session
8. Always let others finish their sentence
9. I speak in the first person (no ONE, WE, IT, YOU)
10. I express my opinion (and do not hide behind questions)
11. I am frank, genuine, honest, and assure all of you my confidentiality.

***Second phase: Work phase: 6th to 20th session***

For dynamic group processes to develop it is important that the therapists do not structure each session in advance and that at least during the first half of most sessions a free process can evolve. Even for the especially important systematic observation of interactions, transference, and countertransference both within the group and between patients and therapist, phases of group interaction are needed that are not determined by structured interventions.

For all patients to feel equally important each session starts with a so-called quick round where everyone in order talks for approximately three minutes about the last few days. There are no strict rules. However, it is pointed out that only reports concerning the four main foci of the intervention (see page 14) should be included. In some of the sessions (see list of details) only “Hook” related topics are covered within the quick round.

Fellow patients are not allowed to interfere in this round; only therapists can ask clarifying questions but should refrain from starting to work through material provided at that stage. Following the round therapists can lead the course of the session and select a central theme of the round according to their intuitive evaluation of the group process.

Working through a topic provided by a particular person should also include other members of the group (eg, by enquiring who has experienced similar feelings, which emotions are triggered in others when listening etc.) At least three central aspects from the initial round should be covered at each session. Even during those phases of the sessions the four crucial areas of the intervention as well as the fact that the entire material can be interpreted upon them remains in the back of the therapist’s head.

The 6th, 10th, 14th, and 18th session will be designed on the basis of the LifeSkills model by Williams (topics 3, 4, 6, and 7). Those phases take approximately 60 minutes each after which an open and unstructured group phase will take place.

The model of “The Hook“ (15) is also implemented within this phase of treatment (also see the timetable below) where the initial round focuses on affects elicited by “Hook” situations. In open sessions material provided by the participants during the “Hook” sessions will be processed in the framework of a psychodynamic background.

According to Horowitz & Kaltreider (22) it is especially important to systematically observe phenomena of transference and countertransference both within the group as well as between patients and therapists and to include them into the treatment process. Negative affects should be pointed out and analysed in detail. It is important that all patients get the chance to be once the center of attention. With the help of all group members alternative cognitive patterns and ways of behavior will be explored each time which enables the active person to leave a prospective critical interaction without negative feelings. Moreover, biographical situations will also be explored in which, at an early stage, similar patterns have evolved or were observed.

***This results in the following structure:***

6th Session: *LifeSkills* ***3***

7th Session: Specific quick round: The Hook

8th Session: Quick round followed by a mainly unstructured session

9th Session: Quick round and The Hook

10th Session: *LifeSkills* ***4***

11th Session: Quick round and The Hook

12th Session: Quick round followed by a mainly unstructured session

13th Session: Quick round followed by a mainly unstructured session

14th Session: *LifeSkills* ***6***

15th Session: Quick round and The Hook

16th Session: Quick round followed by a mainly unstructured session

17h Session: Quick round followed by a mainly unstructured session

18th Session: *LifeSkills* ***7***

19th Session: Quick round and The Hook

20th Session: Quick round followed by a mainly unstructured session

***Third Phase: 21st to 25th session:***

This phase aims at completion of the treatment and relapse prophylaxis. For each individual patient, details on how to prevent a relapse and how to step out of the maladaptive circle should be identified.

**Intervention technique**

By focusing on group interactions therapists play an active role in gently modulating the group process without structuring it. This can be done by adhering to certain basic rules:

* Role plays are rarely availed of (eg, for “The Hook” or “LifeSkills“). Directive and structuring group activities should only be used within the framework of the cognitive-behavioral elements. Yet, approximately half the sessions contain a quick round in the beginning during which all patients give an account of the past week with which only the therapist is allowed to interfere.
* Clarification of interactions eliciting various negative affects is a central theme of the group process. “LifeSkills“ and “The Hook“ techniques are used to help establish critical self-observation and to facilitate the ability to talk about it. The following questions can be useful in this context:
* “What caused aversive emotions?”
* “What wishes in relation to your interaction partner did you have?”
* “Did you express your own ideas and expectations appropriately?”
* “How did you deal with disappointment and anger?”
* “In what way could the situation be more open next time?”
* ”What could have been achieved by enquiries, explanations, or taking over the other person’s perspective?”

 It is also enquired about where, with whom, and in which constellation the relevant emotion possibly already emerged during childhood or adolescence. Group members will be encouraged to jointly look for new patterns of behavior regarding their negative affectivity. Such scenes and events should repeatedly be talked through so patients can realise that there is help at hand and that it is often useful to talk about their problems.

* Many CHD patients tend to quickly and helpfully offer practical advice on how to deal with situations (“You should’ve done this or that” or else). We do not consider such advice helpful for the group. Therefore, therapists immediately interfere and ask the patients to talk about their own feelings, imaginations, or similar experience instead. Arising wishes, how they are interpreted by the patients and how others react to them in real life and/or in the patients’ imagination are also explored.
* Therapists will immediately point out and correct breaches of communication or interaction rules, i.e. if group members ignore what one person says or if their reaction to it lacks empathy, demonstrates dominance or criticism (i.e. any hurtful reaction). In such cases the therapists interfere to point out what happened and to solve the problem. If such interactions remain unnoticed by the therapists (which can happen easily) then the next session will be started by outlining and commenting on the incorrect interaction. Such malignant behavior should possibly not be left idle as it offers opportunities for in vivo incorporation. It should thus be regarded as being paradigmatic in relation to the patients’ patterns of relationship and bonding and worked on in this context.
* Activities to reduce risk behavior will be enhanced. Patients will receive support and be encouraged to help each other (eg, jointly set up walking groups, jointly attend smoking cessation courses, set up telephone lists, attend CHD sports groups etc.).
* Anger, aggression, and often hidden or openly displayed hostility are likely to evolve within the group process. Therapists need to create an atmosphere of security among patients in order to assure sufficient protection and support in case of verbal attacks by other group members. An atmosphere is fostered where it is allowed to express such emotions; however, they will be worked on afterwards. There should never be any shown aggression or anger that is not later on talked about. This aims at unveiling both the aggressor’s and the victim’s hidden wishes and experiences. By doing so, all group members are enabled to learn that strict and inflexible behavior towards others always mirrors an equally strict position towards oneself. This process of learning that empathy with the opponent is an indicator for reconciliation with oneself is a central theme in all therapeutic interventions.

g. As the percentage of female patients is usually too low for a female only group led by a female therapist to be set up (though it might be favourable according to recent research), therapists need to prevent female patients from becoming co-therapists. They have to be gently made aware that they often intuitively care a lot about others and thereby come off badly themselves. Moreover, this behavior is explained to them as being a source of stress and negative emotions.

h. Interpretations in accordance with psychodynamic theory (hidden, conflict-loaden content of present interactions with the therapist or other group members will be explored) are desired and accepted within the frame of group therapy. However, within the therapists’ activity the intervention on current group interactions is central and always based on the four main areas described above. Hereby, according to Heigl-Evers & Ott (23), an interactional psychodynamic group therapy is created.

# Concluding remarks

Group therapy as part of a controlled randomized trial is generally loaded with difficulty as it is not possible for the group leader to select participants and to give grounds for the intervention. This indicates that a group will always contain sceptical persons, especially in a patient group primarily defining themselves as physically, not mentally ill. These patients need to be motivated for such a group process first of all. Therefore, there is a need to introduce structuring elements so that participants feel that they can learn something important and solid from group sessions. On the basis of potentially difficult motivational factors within an interventional study, the group size should not exceed 8-10 patients.

**A1.4 Treatment integrity**

Treatment integrity includes the following dimensions:

a) adherence: use of interventions prescribed and avoidance of those discouraged by the manual;

b) competence: skills in performing interventions in an adequate context.

A treatment coordinating unit is responsible for the establishment of high and com­parable levels of treatment integrity and its continuous evaluation in all trial sites. For that purpose, treatment-specific measures of manual adherence and competence of therapists are applied.

This manual has specified a number of items fundamental for the treatment of coronary patients with comorbid depression. Based on these items, a rating scale has been created and standards for acceptable adherence and competence have been defined before including the first patient. As the individual part of the intervention is mainly supportive, the rating scale for the *individual* intervention is based on the supportive subscale of the SET-specific, reliable and valid scale for adherence and competence (PACS-SE: 24), supplemented by ratings regarding the therapeutic principles specified (esp. coping/ resource orientation, avoidance of rash interpretations/ induction of shame). Rating scales for the *group intervention* were constructed specifically on the basis of this manual. Development of group cohesion as the major intervention goal in the first phase of group treatment is measured by the Group Climate Questionnaire (25).

Training

In order to be included in the trial, the therapists must have completed clinical training in psychodynamic psychotherapy as well as sufficient experience with group psychotherapy. Beginners and trainees were not allowed. Age, sex, extent of clinical training and clinical experience of the therapists are documented.

Trial-specific training of therapists:

As specified in this manual, the intervention consists of two phases, an individual intervention with 3 sessions. For those who continue to be depressed, the second phase consists of an extended group intervention. Based on this manual, therapists must be trained in delivering the individual and group interventions. Before the start of the main study, J. Jordan videotaped a group therapy according to the principles described in this manual, which serves as a basis for training the trial psychotherapists.

The specific competence of the therapists in conducting the manualised treatments is established by a 40 hrs. training program offered by the treatment coordinating unit.

Training of adherence raters:

It is intended to keep the number of raters to a minimum and to perform the ratings by one central rater if at all possible. Raters receive 60 hrs. of training before the intervention starts. Training is based on the discussion of 12 video tapes from the pilot phase. For the determination of interrater reliability, an additional 18 tapes will be used, if more than one rater needs to be recruited.

Feedback and control of adherence during the trial:

Feedback on adherence and competence is given continuously by the local supervisors. In addition, on the basis of the video recordings the treatment coordinating unit will give feedback if a therapist falls below a “yellow line” (level below which a therapist´s adherence or competence is not considered adequate). Should therapists fall below the standards specified, they will receive additional supervision. Should that procedure not remedy their performance, therapists will be withdrawn from the study.

**Implementation**

In order to be included in the trial, therapists need to demonstrate a sufficient level of competence in the treatment of at least 3 short-term interventions with coronary patients before conducting trial therapies. Additional measures include the following:

1. All treatment sessions of the trial (individual and group) will be videotaped.
2. After each session, therapists will rate their interventions on a checklist of specific interventions as described in the manual.
3. Raters of treatment integrity have received training as described above
4. For statistical analysis of treatment integrity, video tapes of one session (out of three) per individual treatment and three randomly drawn sessions of each group of patients (one from the first, second, and third phase each) are evaluated by the trained, independent rater.

**A2: Details of sample size calculation**

Based on pilot data, mean values were expected to be reduced from 10 to 8 in the usual care arm and from 10 to 7, i.e. into the upper normal range, in the intervention arm. In previous observational studies of cardiology patients we found a one-point difference on the HADS-D to be associated with a 9-13% difference in mortality rates (26,27), supporting the potential for also improving life expectancy by means of the trial intervention.

To maximize power of the primary fixed effects analysis, we did not account for the clustering by therapy group. Post-hoc we found an intra-class correlation of 0.15, 18 months after centeration, which corresponds to a design effect of about 2 (≈1+(8-1)\*0.15, assuming an average of 8 participants per group) (28). Thus, given our cautious sample size calculation for crossed subgroup characteristics, the study seems well powered to address its primary objectives, even when accounting for clustering in the analysis.

**A3: Details of randomization**

Treatment arms were balanced by Pocock’s minimisation method according to study center, sex, Type D pattern, socioeconomic status, severity of heart failure, myocardial infarction, recent coronary revascularisation, diabetes, anxiety disorder, presence of major depressive episode, use of antidepressant medication and current psychotherapy. The allocation sequence was dynamically created and remained concealed since local investigators were masked to the characteristics of patients from other centers.

**A4: Details of monitoring and data quality control**

Participating centers were visited on a regular basis. All data were stored in a validated instance of the MACRO electronic data capture system (InferMed Ltd., London, UK) and checked for completeness, plausibility, and correctness automatically during data entry and manually thereafter. A Data Safety and Monitoring Board (DSMB) was established to monitor all serious adverse events (SAEs) and, possibly, to give advice regarding any need for premature termination of the study.

The following events were considered Serious Adverse Events, whether they were related to the intervention or not:

* Any fatal or life-threatening event
* Any event requiring or prolongating hospitalization
* Any event leading to permanent disability
* Any event requiring medical intervention to prevent permanent disability.

This included, among others

* Cardiac and non-cardiac death
* Acute coronary syndromes
* Coronary surgery or interventions
* Severe non-cardiac disease such as cancer
* Newly diagnosed severe mental illness, eg, severe depression, suicide (attempt), psychosis

**B: Supplemental results**

**B1: Per protocol analyses**

A “per protocol” analysis included all patients with valid baseline and 18 months assessments, who attended either (in the psychotherapy arm) at least one individual session and, if still depressed at 4 weeks, at least 50% of group sessions or (in the usual care arm) the single information session. This analysis showed that mean HADS depression scores in psychotherapy patients (n=110) improved from 10.1 ± 2.8 at baseline to 7.6 ± 4.5 at 18 months, while in the usual care arm (n=194) it declined from 10.3 ± 2.4 to 8.2 ± 3.7. The adjusted difference in change from baseline to 18 months between arms was -0.2 (95%-CI -1.2 to 0.8, p=0.686, ANCOVA) in favor of the psychotherapy arm.

**B2: Secondary outcomes for depression**

As for the HADS, also the secondary depression outcomes showed a significant (p<0.001) overall decrease in depressive symptoms but no significant difference between treatment arms. Specifically, scores on the 21-item HAM-D declined from 11.0 ± 6.5 to 8.8 ± 6.8 in the psychotherapy arm and from 11.6 ± 6.6 to 9.1 ± 7.0 in the usual care arm (treatment contrast: p=0.862). The percentage of patients with SCID-diagnosed major depression was significantly reduced in both arms, i.e., from 36.1% to 19.7% (McNemar test: p<0.001; n=203) in the psychotherapy arm and from 36.5% to 20.1% (p<0.001; n=204) in the usual care arm. Again, the difference between treatment arms at 18 months was not significant (chi-square test: p=0.921).

**B3: Participation in treatment and usefulness of the stepwise protocol**

In the first phase of the intervention, 91.6% of patients from the psychotherapy arm received at least one psychotherapy session with a median of 3. In the usual care arm, 87.7% of patients received the information session. At 4-6 weeks after inclusion (T1), the HADS was completed by 85.6% of the psychotherapy patients and 89.1% of the usual care patients. Again, depression scores decreased significantly from baseline to T1 (p≤0.04) but no treatment effect could be observed (p=0.842, ANCOVA).

In the psychotherapy arm, 172 patients still scored above the cutoff on the HADS at T1 and were offered group psychotherapy. Of these, 123 (69.5%) attended at least one of the 25 group sessions. For these group participants the median group attendance was 16 sessions (range 1 to 25). Both intervention and usual care arms improved significantly (p<0.001) but there was no significant difference between arms (p=0.442). In addition, there was no correlation between the number of sessions attended and the change in depressive symptoms in the psychotherapy arm (Spearman’s rho=0.03, p=0.698).

**B4: Mental health treatments and cardiac rehabilitation received outside the trial**

At baseline, 12.1% of all patients (11.6% in psychotherapy arm vs. 12.6% in usual care arm) were treated with antidepressants and 11.1% (10.9% in psychotherapy arm vs. 11.2% in usual care arm) had been in psychotherapy at some point during the year before entering the trial, with no relevant difference between treatments. During the trial, 27.7% of patients in the psychotherapy arm and 24.2% in the usual care arm reported the use of antidepressants on at least one assessment up to 18 months. At 18 months, 14.4% of patients in the psychotherapy arm and 12.6% in the usual care arm received antidepressant medication. We could not see any relevant effect (or interaction with the study treatment) of receiving antidepressants. Moreover, 36.1% of patients in the psychotherapy arm and 35.8% in the usual care arm reported they had seen a mental health professional outside the trial. None of these comparisons between treatment arms was statistically significant. Furthermore, external mental health treatments received during the trial were similar between study arms and unrelated to change in depressive symptoms from baseline to 18 months. The difference in change on the HADS-D between psychotherapy and control group was -0.248 (-0.935 to 0.438), p=0.478, for patients with no external mental health treatments vs. -0.117 (-1.218 to 0.985), p=0.835, for patients with any external mental health treatment. (external treatment\*trial arm interaction: p=0.958).

Approximately 38% of patients had received cardiac rehab immediately before or during the trial with no difference between study arms. Patients with and without early rehab didn’t differ on HADS depression scores at any time point and rehab was unrelated to treatment efficacy (interaction for rehab\*trial arm on change in HADS-D: p= 0.903).

**C: Supplemental figure: Subgroup analysis by center**



**D: Supplemental References**

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1. All examples taken from ref. 11 [↑](#footnote-ref-1)